IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARION L. KNIPE, Individually and as Administratrix and Administratrix Ad Prosequendum of the Estate of HAROLD STANLEY JAKE GARRISON, Deceased, and HAROLD L. GARRISON, JR., Individually,	:	CIVIL ACTION
Plaintiffs,	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

MEMORANDUM

BUCKWALTER S.J. September 30, 2008

Currently pending before the Court are (1) Defendant GlaxoSmithKline's Motion for Summary Judgment on Plaintiffs' Causes of Action, (2) the Response of Plaintiffs Harold L. Garrison, Jr., individually, and Marion Knipe, individually and as administratrix and administratrix *ad prosequendum* of the Estate of Harold Stanley Jake Garrison, and (3) Defendant's Reply Brief. In addition, the Court jointly considers Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of its Motion for Summary Judgment (Causes of Action) and Defendant's Response thereto.

This motion is the second of its kind in this case. The litigation commenced on July 10, 2006, when Plaintiffs sued Defendant for the wrongful death of sixteen-year old Harold Stanley Jake Garrison ("Jake" or "Jake Garrison"), who committed suicide after taking Paxil, an

antidepressant medication manufactured and sold by GlaxoSmithKline ("GSK"). Plaintiffs' claims allege that GSK breached its state law duty to warn of the increased risk of suicide in pediatric users of the drug. Defendant originally moved for summary judgment on the grounds that Plaintiffs' state tort claims were preempted by federal law, *i.e.* the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and its implementing regulations. On August 28, 2008, the Court denied that motion in its entirety. Defendant again seeks summary judgment, this time alleging that each of Plaintiffs' causes of action fails as a matter of law. For the following reasons, the Court grants the motion in part and denies it in part.

I. BACKGROUND AND UNDISPUTED FACTS[1]

A. Jake Garrison's Paxil Use and Suicide

In February 2001, deceased Plaintiff Jake Garrison was referred to dermatologist Booth Durham, M.D. for treatment of his acne. (Pls.' Ex. 153, Booth Durham Dep. ("Durham Dep.") 11:8-17:8, Sep. 5, 2007.) Originally, Dr. Durham treated Jake with Accutane. (Id. at 15:2-16.) In light of the drug's labeling, the doctor informed Jake and his mother that the drug could cause suicidal behavior, and required them to sign a consent form. (Id. at 15:17-17:12; Pls' Ex. 154, Marion Knipe Dep. ("Knipe Dep.") 123:11-124:16, Jan. 11, 2007.) The Accutane course of treatment was completed in August or September 2001. (Durham Dep. 21:13-22:2.)

[1] The Court's summary constitutes a ruling on Plaintiffs' Motion to Strike Evidence submitted by Defendant in support of its Motion for Summary Judgment on Plaintiff's Causes of Action. Specifically, Plaintiffs object to all of Defendant's exhibits with a blanket allegation of lack of authenticity. Although Defendant offers a lengthy response detailing the basis of authenticity for each of the exhibits, Plaintiffs' vague, two-page motion does not warrant such extensive discussion. To the extent, the Court cites a particular piece of evidence, we overrule any objection thereto. To the extent a particular fact or piece of evidence is not cited, the Court has simply deemed that evidence irrelevant to a ruling on this motion, and thus denies the motion to strike.

On January 10, 2002, Jake, who was fifteen years old at the time, returned to Dr. Durham. (Id. at 22:3-23:12.) Jake had been complaining of nausea and redness on his face, and had been refusing to go to school. (Knipe Dep. 110:8-21; 132:4-133:6.) At the time, however, Dr. Durham observed no signs of suicidal ideation. (Durham Dep. 52:23-53:7.) As a result of Jake's self-consciousness, Dr. Durham diagnosed Jake with body dysmorphic disorder,[2] for which he prescribed a fifteen-day supply of Paxil. (Id. at 23:12-25:21.) The dosage was to increase to twenty milligrams after two weeks. (Id. at 25:16-25:21.) This was not the first time Dr. Durham had prescribed Paxil for a patient. (Id. at 27:1-27:9.) Upon prescribing Paxil to Jake, Dr. Durham claims to have told Marion Knipe, Jake's mother, that body dysmorphic disorder could worsen depression, cause further withdrawal, inhibit sleeping, increase hostile behavior, and lead to suicidal ideation. (Id. at 25:6-26:25.) Ms. Knipe testified that she could not recall Dr. Durham saying anything about suicide or suicidal ideation, particularly with respect to Jake's use of Paxil. (Knipe Dep. 125:5-19, 134:18-135:11.)

Jake refilled a thirty-day prescription for Paxil twenty milligrams, on January 27, 2002. (Defendant's Statement of Undisputed Facts on Causes of Action Motion ("DSUF Causes of Action") ¶ 31, Ex. L.) During Jake's February 7, 2002, follow up visit, Dr. Durham remarked that Jake was tolerating Paxil well, was not having any side effects, and "[felt] good about himself." (Durham Dep. 41:18-25; DSUF Causes of Action ¶ 24, Ex. M.). He was to continue Paxil twenty milligrams daily. (DSUF Causes of Action, ¶ 36, Ex. M.) Jake refilled another thirty-day supply for Paxil twenty milligrams on April 8, 2002. (Id. ¶ 38, Exs. J, L.) For reasons

[2] "Body Dysmorphic Disorder" is "a psychosomatic (somatoform) disorder characterized by preoccupation with some imagined defect in appearance in a normal-appearing person." STEDMAN'S MEDICAL DICTIONARY, 116700 (27th ed. 2000).

unknown to Plaintiff Knipe, Jake stopped taking Paxil sometime in April or May. (Id. ¶ 38, Ex. O, Daneen Spitaletto Dep. ("Spitaletto Dep.") 90:2-7, Jan 10, 2008; Knipe Dep. 146:2-7:18.) Jake next returned to Dr. Durham on August 21, 2002, at which time the doctor noted that Jake's acne was starting to flair and that Jake had "not needed" Paxil for a few months. (Durham Dep. 32:19-25.) Dr. Durham remarked that Jake seemed fine that day and had no notation about the redness that seemed to be the original basis of the body dysmorphic disorder. (Id. at 35:16-36:3.)

On September 11, 2002, the first day of Jake's junior year of high school, Jake vomited at school. (DSUF Causes of Action ¶ 45, Ex. Q; Knipe Dep. at 159:11-160:4.) According to investigative reports, Jake had told his mother that kids were teasing him due to his face turning red.[3] (DSUF Causes of Action ¶ 46, Exs. Q and R, Lona Ecker Dep. ("Ecker Dep.") 33:4-21, Apr. 1, 2008.) Jake refilled another Paxil twenty milligram prescription that day, without contacting Dr. Durham, and took the medicine for three days. (DSUF Causes of Action ¶47-48, Ex. J; Durham Dep. 34:18-21.) On September 14, 2002, Jake committed suicide by gunshot. (DSUF Causes of Action ¶ 49.)

At the time of the prescriptions and refills described above, the label for Paxil contained the following statement in the "PRECAUTIONS" section:

> Suicide: The possibility of a suicide attempt is inherent in depression and may persist until significant remission occurs. Close supervision of high-risk patients should accompany initial drug therapy. Precautions for Paxil should be written for the smallest quantity of tablets consistent with good patient management, in

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[3] Plaintiffs dispute this allegation, citing to deposition testimony from Jake's mother, father and sister, who stated they were not aware of their son being teased or bullied at school. The referenced depositions, however, only suggest that Jake generally did not get teased or bullied at school and do not refute Defendant's specific allegation that Jake was teased on September 11, 2002 due to redness in his face. (Pls.' Ex. 161, Harold Garrison Dep. ("Garrison Dep.") 116:3-118:13, Jan. 12, 2007; Knipe Dep. 72:3-4; Spitaletto Dep. 113:19-114:11.)

order to reduce the risk of overdose.

(Pls' Ex. 35 at 1610.) The 2002 label also included, in a section entitled "Other Events Observed During the Premarketing Evaluation of Paxil" (under the sub-heading "Nervous System"), the adverse reaction of "emotional lability," which was identified as a "frequent event." (Id. at 1614.) Under the section entitled "Pediatric Use," the label stated, "Safety and effectiveness in the pediatric population have not been established." (Id. at 1611.)

Dr. Durham knew that Paxil had not been approved by the Food and Drug Administration ("FDA") for use by pediatric patients at the time he prescribed it to Jake, but nonetheless gave it to him "[b]ecause [he] was comfortable with that medication. And [he] had had good results in other pediatric patients with body dysmorphic disorder with it." (Durham Dep. 37:24-38:14.) As a result of the FDA's addition of the black box warning on pediatric use, however, Dr. Durham no longer prescribes Paxil for pediatric patients since, according to his understanding, "it may give them enough energy to actually commit suicide." (Id. at 57:16-57:23.)

Dr. Durham testified that he had seen an advertisement for Paxil or Paxil CR in journals, but not on television. (Id. at 75:9-13.) He had never, however, seen any brochures or patient information that was left in his department or office from GSK pertaining to Paxil, nor had he ever met with a representative from GSK regarding Paxil. (Id. at 75:18-76:16.) Nonetheless, Dr. Durham explained that he reads the Physician's Desk Reference ("PDR") several times a week to obtain information about medications. (Id. at 72:10-73:12.) In addition, his other sources of information for his prescribing practices include journals, conferences, tapes, and lectures. (Id. at 73:13-18.) He is also aware of Medical Letters, wherein manufacturers announce their changes in medications. (Id. at 73:19-25.) Although Marion Knipe never saw advertisements for Paxil

(Knipe Dep. 30:13-15), Jake's father, Harold Garrison had seen "quite a lot" of television commercials for Paxil prior to Jake taking Paxil. (Garrison Dep. 15:17-17:5.)

B. GSK's Regulatory Efforts to Obtain FDA Approval of a Pediatric Indication for Paxil[4]

Paxil is generally classified as a selective serotonin reuptake inhibitor ("SSRI"), currently approved on a prescription basis only for the treatment of depression, obsessive compulsive disorder, panic disorder, social anxiety disorder, generalized anxiety disorder, post-traumatic stress disorder and premenstrual dysphoric disorder in adult patients. (Defendant's Statement of Undisputed Facts for Federal Preemption Motion ("DSUF Preemption"), Ex. A, Arning Decl. ("Arning Decl.") ¶ 5.) On November 20, 1989, SmithKline Beecham Pharmaceuticals ("SB")[5] filed a new drug application ("NDA") for paroxetine ("Paxil") seeking FDA approval for the treatment of depression in adults. (Arning Decl. ¶ 19.) In support of this application, SB submitted data to the FDA, including toxicology data, animal studies and clinical studies in humans, as well as data on suicides, suicide attempts and suicidal behavior. (Id. ¶ 21.) After extensive study, the FDA issued an approval letter for Paxil on December 29, 1992, making clear that approval was conditioned on the use of the FDA-approved prescribing information accompanying the letter. (Id.) The original FDA-approved labeling did not include any warning

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[4] This Court set forth an extensive regulatory history for Paxil in the August 28, 2008 opinion on Defendant's Motion for Summary Judgment on the grounds of preemption. Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 2008 WL 4090995 (E.D. Pa. Aug. 28, 2008). Rather than repeat that history in its entirety, the Court incorporates the previous discussion by reference and recites the more salient points with respect to GSK's efforts to obtain FDA approval for a pediatric indication of Paxil.

[5] SB merged with GlaxoWellcome in December 2000 to form GlaxoSmithKline PLC. (Arning Decl. ¶ 1 n.1.)

or other statement regarding an increased risk of suicide or suicidality from using Paxil. (Id. ¶ 28, Exs. 5 and 6.) Indeed, the only references to "suicide" or "suicide attempt" appeared in the description of "a major depressive episode" and a precaution that suicide is "an inherent risk in depressed patients." (Id. ¶ 28, Ex. 5.) In the approval letter, however, the FDA stated, "[p]lease consider conducting post-approval studies with [Paxil] in depressed children and adolescents. Depression is common in these populations and it is likely that [Paxil] will be used in children and adolescents, despite the absence of any relevant data. Consequently, we feel it would be useful for you to obtain data pertinent to the safety and efficacy of [Paxil] in these groups." (Id.)

On April 11, 2002, GSK filed a supplemental NDA to the FDA "proposing the use of Paxil to treat children and adolescents with major depressive disorder and obsessive compulsive disorder."[6] (Pls.' Exs. 36, 37.) In connection with its application, GSK submitted Study 329 and Study 377, both of which had been completed in 1998, and Study 701, which was completed in January 2001. (Id.) On October 7, 2002, Dr. Andrew Mosholder, the FDA reviewer of the pediatric Supplemental NDA for Paxil completed his review. In the section of his report regarding efficacy, he stated:

> For Study 377: "This trial did not provide any evidence that paroxetine is active in the treatment of adolescent MDD [major depressive disorder]."
>
> For Study 701: "This trial did not provide any evidence that paroxetine is effective in the treatment of pediatric MDD."
>
> For Study 329: "[T]his trial should be considered a failed trial, in that neither active treatment group showed superiority over placebo by a statistically

[6] Although Defendant argues that GSK only sought approval for an indication in pediatric obsessive compulsive disorder, not major depressive disorder, that contention is not confirmed by the evidence submitted by Defendant. (Def.'s Ex. 21, David Wheadon Dep., 239-44, May 9, 2007.)

> significant margin."

(Pls.' Ex. 39.)[7] In his report regarding safety, Dr. Mosholder stated:

> The most prominent adverse reactions not seen in corresponding adult trials appear to involve behavioral effects; these events were coded with terms such as hostility and emotional lability. As previously noted, the sponsor's method of coding these events was potentially confusing, and thus additional information will be helpful for the purpose of definitively assessing the potential behavioral toxicity for paroxetine in pediatric patients. . . . Further assessment of the safety profile will have to await the sponsor's reply to requests for additional information.

(Id.) Accordingly, on October 21, 2002, the FDA issued a letter to GSK requesting additional information and clarification, including "an expanded version of [a table of adverse events coded under the terms hostility, emotional lability or agitation], including all psychiatric and behavioral adverse events, and also those that occurred among placebo patients" and GSK's "rationale for coding suicide attempts and other forms of self-injurious behavior under the . . . term 'emotional lability.'" (Pls.' Ex. 40.)

In May of 2003, seven months after the FDA's request for clarification as to GSK's study results, GSK submitted a supplement in partial response to the FDA's October 10, 2002, letter. In response to this submission, the FDA drafted a "Request for Consultation" memo, dated June 5, 2003, noting that GSK's re-analyzed data, clarifying what events were included under the term "emotional lability," suggested an excess risk of suicidality in patients taking Paxil compared to those taking the placebo. (Pls.' Ex. 48.) At that time, GSK had not proposed labeling changes. (Pls.' Ex. 47.)

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[7] On October 10, 2002, the FDA sent a letter to GSK stating that "Studies 329, 377 and 701 failed to demonstrate the efficacy of Paxil in pediatric patients with MDD. Given the fact that negative trials are frequently seen, even for antidepressant drugs that we know are effective, we agree it would not be useful to describe these negative trials in labeling." (Pls.' Ex. 40.)

On June 19, 2003, the FDA issued a Talk Paper reporting that it was "reviewing reports of a possible increased risk of suicidal thinking and suicide attempts in children and adolescents under the age of 18 treated with the drug Paxil for major depressive disorder." (Arning Decl. ¶ 42, Ex. 23.) The advisory stated, "[a]lthough the FDA had not completed its evaluation of the new safety data, FDA is recommending that Paxil not be used in children and adolescents for the treatment of MDD, and Paxil is currently not approved for use in children and adolescents." (Id.)

On July 22, 2003, the FDA requested adverse event data from the manufacturers of all "modern drugs" used to treat major depressive disorder, in order to further assess suicidality in pediatric patients enrolled in clinical studies. (Pls.' Ex. 55.) The FDA then issued a Public Health Advisory and corresponding Talk Paper, on October 27, 2003, stating that the "data do not clearly establish an association between the use of these drugs and increased suicidal thoughts or actions by pediatric patients," but it was "not possible at this point to rule out an increased risk of [increased suicidal thoughts or actions] for any of these drugs, including Paxil." (Pls.' Ex. 58.) In February 2004, the FDA advisory committee convened and recommended that the FDA issue an immediate warning concerning the potential risk of suicidality in pediatric patients and agreed that the data should be analyzed further. (Pls.' Ex. 62.) On March 22, 2004, the FDA issued a Public Health Advisory warning of the need to closely monitor adults and children being treated with antidepressants to determine whether there is a worsening of depression. (Arning Decl. ¶ 49, Ex. 30.) It also noted that, after initial reports and studies with Paxil, and subsequent reports on studies of other drugs, there appeared to be "an increased risk of suicidal thoughts and actions in the children given antidepressants." (Id.) In May of 2004, GSK sent a "Dear Healthcare Professional" letter to doctors in the United States alerting them to the

FDA's Public Health Advisory. (Pls.' Ex. 64.)

The FDA advisory committee met again in September 2004, and concluded that the data, in the aggregate, reflected an increased risk of suicidality in pediatric patients, and recommended that the FDA consider new class labeling changes. (Pls.' Ex. 69.) On October 15, 2004, a new Public Health Advisory and letter from the FDA directed manufacturers to add a "black box" warning[8] and expanded warning statements to the labeling of all antidepressant medications, describing the increased risk of suicidality in children and adolescents being treated with antidepressants, and including information about the results of pediatric studies. (Pls.' Ex. 74; Arning Decl. ¶ 55, Ex. 34.) On November 12, 2004, GSK filed labeling supplements to Paxil and Paxil CR NDA's to include the labeling changes requested by the FDA. (Arning Decl. ¶ 56.) On January 26, 2005, the FDA notified GSK that it decided to "modify the new PI [package insert] slightly so that the language in the 'Warnings Section' of the PI more precisely mirrors the language set forth in the black box warning." (Pls.' Ex. 76.)

The FDA approved the labeling supplements for Paxil and other antidepressants, on January 26, 2005, and required the following "black box" warning:

> Suicidality in Children and Adolescents
>
> Antidepressants increased the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder (MDD) and other psychiatric disorders. Anyone considering the use of [insert established name] or any other antidepressant in a child or adolescent must balance this risk with the clinical need. Patients who are started on therapy should be observed closely for clinical worsening, suicidality, or other unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. [Insert established name] is not approved for use in pediatric patients. (See Warnings and Precautions:

[8] According to the FDA, a "black box" warning is the most serious warning placed in the labeling of a prescription medication. (Arning Decl. ¶ 55, Ex. 34.)

Pediatric Use)

> Pooled analyses of short-term (4 to 16 weeks) placebo-controlled trials of 9 antidepressant drugs (SSRIs and others) in children and adolescents with major depressive disorder (MDD), obsessive compulsive disorder (OCD), or other psychiatric disorders (a total of 24 trials involving over 4400 patients) have revealed a greater risk of adverse events representing suicidal thinking or behavior (suicidality) during the first few months of treatment in those receiving antidepressants. The average risk of such events on drug was 4%, twice the placebo risk of 2%. No suicides occurred in these trials.

(Arning Decl. ¶ 59, Ex. 76.)

II. SUMMARY JUDGMENT STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c). A factual dispute is "material" only if it might affect the outcome of the case. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986). For an issue to be "genuine," a reasonable fact-finder must be able to return a verdict in favor of the non-moving party. Id.

On summary judgment, it is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. Boyle v. County of Allegheny, Pennsylvania, 139 F.3d 386, 393 (3d Cir. 1998) (citing Petruzzi's IGA Supermarkets, Inc. v. Darling-Delaware Co. Inc., 998 F.2d 1224, 1230 (3d Cir. 1993). Rather, the court must consider the evidence, and all reasonable inferences which may be drawn from it, in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S. Ct. 1348 (1986) (citing United States v. Diebold, Inc., 369 U.S. 654, 655,

82 S. Ct. 993 (1962)); Tigg Corp. v. Dow Corning Corp., 822 F.2d 358, 361 (3d Cir. 1987). If a conflict arises between the evidence presented by both sides, the court must accept as true the allegations of the non-moving party, and "all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255.

Although the moving party bears the initial burden of showing an absence of a genuine issue of material fact, it need not "support its motion with affidavits or other similar materials negating the opponent's claim." Celotex Corp. v. Catrett, 477 U.S. 317, 323, 106 S. Ct. 2548, 2553 (1986). It can meet its burden by "pointing out . . . that there is an absence of evidence to support the nonmoving party's claims." Id. at 325. Once the movant has carried its initial burden, the opposing party "must do more than simply show that there is some metaphysical doubt as to material facts." Matsushita Elec., 475 U.S. at 586. "There must . . . be sufficient evidence for a jury to return a verdict in favor of the non-moving party; if the evidence is merely colorable or not significantly probative, summary judgment should be granted." Arbruster v. Unisys Corp., 32 F.3d 768, 777 (3d Cir. 1994), abrogated on other grounds, Showalter v. Univ. of Pittsburgh Med. Ctr., 190 F.3d 231 (3d Cir. 1999).

III. DISCUSSION

As discussed above, this case involves a products liability action in which Plaintiffs allege that decedent Jake Garrison was injured by his ingestion of the prescription drug Paxil, manufactured by Defendant GSK. Plaintiffs claim that GSK carelessly and negligently researched, manufactured, sold, merchandised, advertised, promoted, labeled, analyzed, tested, distributed and marketed Paxil, and failed to warn of known dangers in use by pediatric patients. (Compl. ¶ 38.) Based on these allegations of harm, Plaintiffs set forth claims for compensatory

and punitive damages.

A. Applicable Law

At the outset of the Court's analysis, we must first decide the applicable law. Defendant avers that, notwithstanding the pendency of this action within the Eastern District of Pennsylvania, New Jersey law should apply to the substantive claims. Plaintiff, on the other hand, asserts that Pennsylvania has the most significant contacts and, thus, should control the Court's analysis of the various causes of action.

In resolving this dispute, this Court must, pursuant to our diversity jurisdiction, apply the forum's choice of law rules. Chin v. Chrysler, LLC, 538 F.3d 272, 278 (3d Cir. 2008); Shuder v. McDonald's Corp., 859 F.2d 266, 269 (3d Cir.1988). Pennsylvania's choice of law approach adopts a "'flexible rule which permits analysis of the policies and interests underlying the particular issue before the court.'" Coram Healthcare Corp. v. Aetna U.S. Healthcare, Inc., 94 F. Supp.2d 589, 594 (E.D. Pa. 1999) (quoting Griffith v. United Air Lines, Inc., 203 A.2d 796, 805 (Pa. 1964)). It entails three steps. First, the court must determine whether a real conflict exists, that is, whether these states would actually treat this issue any differently. Hammersmith v. TIG Ins. Co., 480 F.3d 220, 229-30 (3d Cir. 2007). If there is no substantive difference between the laws of the competing states, no real conflict exists and forum law applies. Id. at 230; Air Prods. and Chems. v. Eaton Metal Prods. Co., 272 F. Supp. 2d 482, 490 n.9 (E.D. Pa. 2003). Where a real conflict exists, the court moves to the second step and examines the governmental policies underlying each law in order to classify the conflict as true, false or an unprovided for situation. Hammersmith, 480 F.3d at 230. A false conflict occurs where only one state's interests would be impaired, and the law of the interested state applies. LeJeune v. Bliss-Salem Inc., 85 F.3d 1069,

1071 (3d Cir. 1996). Where, on the other hand, each jurisdiction has a governmental policy or interest that would be impaired by the application of the other state's law, a true conflict exists. Id. In the case of a true conflict, the court turns to the third step to "determine which state has the 'greater interest in the application of its law.'" Hammersmith, 480 F.3d at 231 (quoting Cipolla v. Shaposka, 267 A.2d 854, 856 (Pa. 1970). This determination demands that a court weigh the contacts each jurisdiction has with the dispute on a qualitative scale according to the extent they implicate the policies and interests underlying the particular dispute before the court. Id.

Contrary to Plaintiffs' arguments, a real conflict clearly exists between the product liability laws of New Jersey and Pennsylvania. Pennsylvania courts allow claims of negligence and breach of implied warranty to be brought in conjunction with a products liability claim. Torres v. Lucca's Bakery, 487 F. Supp.2d 507, 513 (D.N.J. 2007). On the other hand, New Jersey's Products Liability Act, N.J. STAT. ANN. 2A:58C-1, *et seq.*, subsumes common law products liability claims into one statutory cause of action for strict liability; it does not permit negligence and breach of warranty as separate claims for injuries caused by the defective products. Torres, 487 F. Supp.2d at 513. "When dealing with liability based on negligence, strict liability, products liability or the like, differing rules as to liability or damages generally represent genuine conflicts since the laws covering these issues take into account both the needs of the injured plaintiffs and the economic viability of the defendants." Id. (quoting Boyes v. Greenwich Boat Works, Inc., 27 F. Supp. 2d 543, 548 (D.N.J. 1998); see also Borelli v. Everland, Civ. A. No. 00-5721, 2006 WL 435730, at *3 (E.D. Pa. Feb. 21, 2006) (recognizing the existence of a real conflict between New Jersey and Pennsylvania products liability laws and citing cases).

Turning to the second step, the Court also finds that a true conflict exists. As noted above, both Pennsylvania and New Jersey seek to "compensate people injured by defective products and regulate the conduct of manufacturers and distributors (i.e., ensure production of safe products) within the state." Torres, 487 F. Supp. 2d at 513-14. Each of their respective interests would be impaired by the application of the other state's law.

This determination leads to the third inquiry: which state has the most significant contacts with the litigation. "In making this determination, this Court must look to an array of factors: (i) the place where the injury occurred; (ii) the place where the conduct causing the injury occurred; (iii) the domicile, residence, nationality, place of incorporation, and place of business of the parties; and (iv) the place where the relationship, if any, between the parties is centered." Henderson v. Merck & Co., Inc., Civ. A. No. 04-5987, 2005 WL 2600220, at *7 (E.D. Pa. Oct. 11, 2005) (citing RESTATEMENT (SECOND) OF CONFLICTS § 145). These contacts, however, must only be considered to the extent they relate to the "policies and interests underlying the particular issue before the court." Cipolla, 267 A.2d at 856 (quotations omitted). The focus of the analysis, therefore, must be on the qualitative, rather than the quantitative, weight of the contacts. Id.

In Blain v. SmithKline Beecham Corp., 240 F.R.D. 179, 181, 193 (E.D. Pa. 2007), the court undertook a conflict of laws analysis in a putative products liability action by parents of children who committed suicide while under influence of antidepressant Paxil. The court analyzed almost the identical contacts present in this case – a defendant domiciled in and making decisions regarding Paxil in Pennsylvania, compared with the plaintiffs domiciled, purchasing Paxil, ingesting Paxil, and being injured in other states. Id. at 193. The court concluded that

> There is no way to apply Pennsylvania law to part of the liability determination, as proposed by the plaintiffs, without disregarding the comity afforded the other states whose interests are in protecting their citizens from tortious harm caused within their boundaries. A state's interest in fixing liability for tortious harm caused within its boundaries goes to its interests in protecting its citizens and regulating conduct there. Of course, Pennsylvania has an interest in regulating its citizens' labeling practices. When that conduct reaches and has consequences beyond the state's borders, it affects citizens of other states. When it does, the foreign state's interest in protecting its citizens outweighs Pennsylvania's regulatory concerns.

Id. at 193-94 (footnote omitted).

Likewise, in Henderson v. Merck & Co., Civ. A. No. 04-5987, 2005 WL 2600220 (E.D. Pa. Oct. 11, 2005), a case alleging injuries sustained by the ingestion of a prescription drug, the court, applying Pennsylvania's choice of law rules, considered which state's law applied to the parties' dispute. It noted that the plaintiff had purchased the drugs in Michigan, a physician in Michigan prescribed the drugs at issue, plaintiff's reliance on defendant's representations concerning the drug occurred in Michigan and, most importantly, plaintiff's injuries occurred in Michigan. Id. at *7. By contrast, New York and New Jersey's only contacts involved the defendants' incorporation and transaction of business in those states. Id. The court determined that the importance of New York and New Jersey's contacts was "diluted by the fact that the remaining relevant events took place in Michigan." Id. at *8. "Indeed, because plaintiff is a Michigan resident, because plaintiff purchased, was prescribed, and ingested Bextra within Michigan's borders, and because plaintiff allegedly suffered injuries in Michigan, the interests of [the other states] in applying their product liability laws to such extraterritorial conduct lose vigor." Id.

Finally, in Bearden v. Wyeth, 482 F. Supp. 2d 614 (E.D. Pa. 2006), the court faced a

choice of law question in a case where the plaintiffs' decedent committed suicide after ingesting antidepressant medication manufactured by defendant. Arkansas was the state in which the decedent lived and maintained his residency prior to his death, received all medical care associated with his depression, purchased the antidepressant, received any representations, express warranties or warnings concerning the drug, experienced any reactions to the drug, and committed suicide. Id. at 620. By contrast, defendant was a Delaware corporation, contained its divisional headquarters in Pennsylvania, made all representations and express warranties and warnings from its business in Pennsylvania, and employed personnel responsible for the antidepressant in Pennsylvania. Id. The court recognized that although Pennsylvania had an interest in regulating the activities of the defendant, who maintained a principal place of business there and conducted many activities concerning the subject drug there, "Arkansas ha[d] a greater interest in applying its laws to protect and provide redress for a citizen who was prescribed a drug, received any relevant representations or warnings about it, purchased it, ingested it, and was injured by it – all within his home state of Arkansas." Id. at 621.

Guided by this jurisprudence, this Court finds that New Jersey unequivocally maintains substantively greater contacts with the dispute at bar. Plaintiffs and Jake Garrison resided in New Jersey at all times during the events relevant to this lawsuit. Jake went to a New Jersey physician, Dr. Booth Durham, for medical care. Dr. Durham wrote the Paxil prescription, which Plaintiffs' subsequently filled in New Jersey pharmacies. Any purported representations or warnings to Dr. Durham, Plaintiffs and Jake by Defendant regarding Paxil were received in New Jersey. Finally, Jake suffered all alleged side effects from Paxil and ultimately committed suicide in New Jersey.

The sole contact Pennsylvania maintains with this litigation is as the situs of Defendant's headquarters and principal place of business. Although Plaintiffs attempt to expand the importance of this contact by asserting that all decisions regarding the marketing, testing, proposed labeling and distribution of Paxil were made in Pennsylvania, this argument is unavailing and, as noted above, has been repeatedly rejected by courts within this district.[9] The jurisdiction in which the drug was prescribed and ingested clearly maintains the strongest interest in applying its applicable law to regulate the sale, prescription and ingestion of pharmaceuticals within its borders. See, e.g., In re Diet Drugs, Civ. A. No. 98-20626, 1999 WL 673066, at *15 (E.D. Pa. Aug. 26, 1999) (recognizing place of injury as crucial in choice of law analysis). The mere fact that defendant resides in Pennsylvania and conducts some business there simply does not outweigh New Jersey's dual interests of protecting its citizens and regulating business conduct occurring within its borders. Accordingly, the Court finds that New Jersey law applies

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[9] The two cases cited by Plaintiffs in support of their contention do not apply Pennsylvania choice of law rules and, as such, are inapposite. Moreover, they are distinguishable on their facts. In In re Bendectin Litig., 857 F.2d 290 (6th Cir. 1988), the Sixth Circuit faced a conflicts analysis in a products liability action brought by women who had taken a drug for morning sickness during pregnancy. Id. at 293-94. The court ultimately deemed the law of the state of manufacture as more significant, as opposed to where the plaintiffs happened to live at that time. Id. at 304-05. In doing so, however, the court recognized that the current states of residency were not necessarily either the states of prescription or ingestion of the drug or the states of injury. Id.

The case of Simon v. Philip Morris, Inc., 124 F. Supp. 2d 46 (E.D.N.Y. 2000) is even less compelling. The court in that matter applied the law of New York, where the defendant company was located, to the general liability questions in the case, but applied each individual plaintiff's own state law to questions of individual liability. Id. at 74-75.

Unlike the aforementioned cases, in the case before us, New Jersey is the residency of all plaintiffs, the situs of injury, the state of prescription, the state of purchase and the locus of any potentially improper advertising or promotion. As the parties' relationship was centered entirely in New Jersey, the jurisprudence from within this Circuit suggests that New Jersey law should apply.

to the substantive claims at issue.[10]

B. Substantive Claims

As noted above, Plaintiffs allege claims of fraud, negligent misrepresentation, negligence, negligent pharmaco-vigilance, strict liability and breach of express warranty, all resulting from Jake Garrison's ingestion of Paxil and subsequent suicide. Defendant moves for summary judgment on each of these counts, as well as Plaintiffs' allegations of off-label promotion and claim for punitive damages. The Court addresses each argument individually.

1. Fraud and Negligent Misrepresentation Claims

Defendant initially argues that Plaintiffs' claims for fraud and negligent misrepresentation fail, as a matter of law, on two grounds. First, Defendant asserts that Plaintiffs' claims are subsumed by New Jersey's Product Liability Act ("PLA") and, thus, are not separately cognizable. Second, Defendant contends that, even if such claims are cognizable, Plaintiffs cannot produce any evidence demonstrating reasonable or justifiable reliance sufficient to sustain either of these causes of action.

a. Whether the Fraud and Misrepresentation Claims Are Subsumed by the New Jersey Product Liability Act

New Jersey's Products Liability Act was passed as "remedial legislation to establish clear rules [in] . . . actions for damages for harm caused by products." N.J. STAT. ANN. 2A:58C-1. "It imposes a duty on manufacturers to produce a defect-free product, regardless of fault." Ebenhoech v. Koppers Indus., Inc., 239 F. Supp. 2d 455, 472 (D.N.J. 2002). "To prevail on a

[10] In an alternative argument, Plaintiffs contend that, under the principle of *depecage*, Pennsylvania law should apply to the punitive damages claim. The Court deals with that argument *infra* at Section III.B.5.

products liability action, plaintiff must show: (1) that defendant is a manufacturer, (2) that the product was defective, (3) that the defect existed when the product left defendant's control, (4) that a reasonably foreseeable user was injured, and (5) that the defect was the proximate cause of the plaintiff's injury." Id. [11] A product is "deemed to be defective if it is not reasonably fit, suitable, or safe for the ordinary and foreseeable purpose for which it is sold." Myrlak v. Port Auth. of N.Y. and N.J., 723 A.2d 45, 52 (N.J. 1999).

The PLA defines the term "product liability action" as "any claim or action . . . for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J. STAT. ANN. § 2A:58C-1(b)(3). Section 2, N.J. Stat. Ann. § 2A:58C-2, "establishe[s] the sole method to prosecute a 'product liability action.'" Estate of Edward W. Knoster v. Ford Motor Co., 200 Fed. Appx. 106, 115 (3d Cir. 2008) (quoting Tirrell v. Navistar Int'l, Inc., 591 A.2d 643 (N.J. Super. App. Div.1991). Thus, under New Jersey products liability law, negligence and implied breach of warranty are no longer viable as separate claims for harm caused by a defective product. N.J. STAT. ANN. § 2A:58-C1; Reiff v. Convergent Techs., 957 F. Supp. 573, 583 (D.N.J. 1997). Because the PLA generally subsumes common-law product liability claims, "the Third Circuit, the New Jersey District Court, and New Jersey State courts consistently have dismissed product liability claims based on common-law theories when those theories allege 'harm caused by a product.'" Brown ex. rel. Estate of Brown v. Philip Morris, Inc., 228 F. Supp.2d 506, 516 (D.N.J. 2002) (citing cases).

New Jersey federal and state courts have, on several occasions, determined that negligent

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[11] Under the PLA, three types of defects are actionable: (1) manufacturing defects; (2) failure to warn defects; and (3) design defects. N.J. STAT. ANN. 2A:58C-2. The parties appear to agree that the only category at issue here is a failure to warn defect.

misrepresentation and fraud claims are among the claims subsumed by the FDA. For example, in Walus v. Pfizer, 812 F. Supp. 41, 42 (D.N.J. 1993), the recipient of a prosthetic heart valve sued the valve manufacturer and pharmaceutical company, asserting theories of negligence, strict liability, failure to warn, fraud, misrepresentation, and negligent and intentional infliction of emotional distress. The court held that "New Jersey treats all product liability actions the same, regardless of the theory asserted." Id. at 45. Accordingly, it determined that notwithstanding plaintiff's attempt to recast his claim in terms of fraud, he was still bound by the elements of the PLA. Id.

More recently, in Lopienski v. Centocor, Inc., Civ. A. No. 07-4519, 2008 WL 2565065, at *1 (D.N.J. June 25, 2008), the plaintiff alleged injury as a result of her use of the prescription drug medication Remicade. In her complaint, she claimed that defendants "designed, created, manufactured, packaged, labeled, distributed, marketed, sold, promoted and/or advertised Remicade, and/or controlled such processes." Id. Based on these allegations of harm, Plaintiff asserted claims for compensatory and punitive damages pursuant to strict liability, negligence, fraud and consumer fraud law. Id. The Court found that "the NJPLA subsumes all causes of action for physical injury caused by a product." Id. at *1 n.2. Accordingly, the Court concluded that plaintiff's claims for negligent misrepresentation, fraudulent misrepresentation, consumer fraud pursuant to the New Jersey Consumer Fraud Act and fraud by concealment fell within the PLA's ambit. Id.; see also Brown, 228 F. Supp. 2d at 517 (plaintiff asserted a fraud claim based on the allegation that plaintiff contracted cancer from smoking cigarettes; the court found that such claims essentially recasted the product liability claims, and thus fell within the ambit of the

PLA.)[12]

In the face of this jurisprudence, the Court likewise finds that, to the extent that Plaintiffs assert fraud and negligent misrepresentation based on the allegation that Paxil was not reasonably fit for its intended use because of inadequate warnings, such claims are subsumed by the PLA. N.J. STAT. ANN. 2A:58C-2(b). In turn, they are not separately cognizable and must be dismissed.

Our analysis of these two causes of action, however, does not end at this juncture. In Wendling v. Pfizer, 2008 WL 833549 (N.J. Super. Ct. App. Div. Mar. 31, 2008), the New Jersey Superior Court recognized a distinct exception to the general principle of subsumption. In that case, the owners of a horse, which allegedly died as a result of a tapeworm infestation, brought an action against the manufacturer of a veterinary product for common law negligent misrepresentation and violation of Consumer Fraud Act, alleging that the advertisement for the product was false and misleading. Id. at *1-2. The plaintiffs did not claim that the drug was not reasonably fit for its intended use because it failed to contain adequate warnings or instructions. Id. at *8. "Instead, they alleged that there was a misleading, false or materially deficient product advertisement. In other words, it was not the product itself that caused the harm, but allegedly its misleading promotion." Id. Under such circumstances, the court concluded that the plaintiffs'

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[12] Plaintiffs attempt to distinguish Brown by noting that the court found subsumption of the fraud claims due only to the failure of plaintiff's counsel to cite to contrary authority. Such an interpretation of that case is misleading. The court in that matter clearly considered the current law on the PLA and subsumption of fraud claims prior to concluding that plaintiff's claims were indeed subsumed. Id. at 516-17. Its remarks that plaintiff's counsel cited to no contrary authority does not suggest that the court itself did not search for such authority. Id. Moreover, plaintiffs' citation to a law review article published in the Seton Hall Law Review, see William A. Drier, "Direct-to-Consumer Advertising Liability: An Empty Gift to Plaintiffs," 30 SETON HALL L. REV. 806, 807 (2000), is unavailing. Aside from the fact that this article does not clearly support Plaintiffs' position, it is not binding or even persuasive authority.

negligent misrepresentation claim was not subsumed by the PLA. Id.

In the case at bar, the Complaint clearly alleges, in addition to the adequate warning claim, that Defendant "negligently and carelessly promoted Paxil as safe and effective for use with pediatric patients when, in fact, it was neither safe nor effective." (Compl. ¶ 38(f).) In other words, Plaintiffs contend that Defendant improperly marketed Paxil for off-label pediatric use without disclosing – and actually concealing – the negative effects. Such claims, like those in Wendling, do not allege injury by Paxil itself, such that the PLA would encompass the claims. Rather, they claim injury by the allegedly faulty advertising campaign for Paxil. These claims, according to reigning New Jersey jurisprudence, are not subsumed by the PLA and, thus, warrant consideration here.

b. Whether Plaintiffs' Fraud and Negligent Misrepresentation Claims Fail as a Matter of Law

Perhaps in recognition of this exception, Defendant alternatively argues that the fraud and negligent misrepresentation claims fail because Plaintiffs have no proof of reliance by either themselves or the prescribing physician, Dr. Booth Durham. Upon consideration of the record, the Court finds that a genuine issue of material fact exists.

To establish a *prima facie* case of common law fraud, a plaintiff must show: "(1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages." Gennari v. Weichert Realtors, 691 A.2d 350, 367-68 (N.J. 1997). "Every fraud in its most general and fundamental conception consists of the obtaining of an undue advantage by means of some act or omission that is unconscientious

or a violation of good faith." Jewish Ctr. of Sussex County v. Whale, 432 A.2d 521, 524 (N.J. 1981); Port Liberte Homeowners Ass'n, Inc. v. Sordoni Const. Co., 924 A.2d 592, 601 (N.J. Super. Ct. App. Div. 2007) (quoting Jewish Ctr., 432 A.2d at 524). To establish a claim of negligent misrepresentation, a plaintiff must prove that an incorrect statement was negligently made and justifiably relied upon to recover damages for economic loss or injury sustained as a consequence of that reliance. H. Rosenblum, Inc. v. Adler, 461 A.2d 138, 142-43 (N.J. 1983); Gross v. Johnson & Johnson-Merck Consumer Pharms. Co. 696 A.2d 793, 797 (N.J. Super. Ct. Law Div. 1997).

Defendant, for purposes of only this claim, does not contest Plaintiffs' argument that GSK engaged in "aggressive promotional activities" representing that Paxil was safe and effective.[13] (Compl. ¶ 70.) Instead, Defendant limits its argument to the reliance prong of the fraud and negligent misrepresentation tests, contending that "Plaintiffs cannot produce any evidence demonstrating that GSK made any representation to them or Dr. Durham upon which either relied." (Def.'s Mem. Supp. Mot. Summ. J. 8.) Specifically, it points to Plaintiff Harold Garrison's admission that he never attended any of Jake's doctor visits. (Garrison Dep. 58:1-2.) Likewise, Plaintiff Marion Knipe was unable to recall anything she learned about Paxil from Durham and, in fact, stated that Dr. Durham told her nothing about Paxil. (Knipe Dep. 121:21-122:23; 125:5-127:14.)

[13] In a later section of its motion, Defendant does challenge Plaintiffs' argument that GSK engaged in off-label promotion. Some of the specific promotional activities at issue, which constitute the allegedly overt fraudulent misrepresentations, are discussed *infra*, Section III.B.2.

Moreover, Defendant cites the following deposition testimony of Dr. Durham[14] to establish that he did not rely on any promotional activities by GSK in making his decision to prescribe Paxil to Jake Garrison:

> Q. Have you ever had a sales representative from GlaxoSmithKline come talk to you about Paxil?
>
> A. I do not believe so. I've had GlaxoSmithKline reps with their topical products, but . . .
>
> Q. So to the best of your knowledge, you don't think you've ever discussed Paxil with any GlaxoSmithKline sales rep?
>
> * * *
>
> A. It's possible but I don't believe so.

(Durham Dep. 31:9-20.)

> Q. Have you ever seen an advertisement for Paxil or Paxil CR?
>
> A. I believe so, in the journals. I don't know if they advertise on television. But yes.
>
> Q. And have you ever seen an advertisement for any SSRI –
>
> A. Yes.
>
> Q. – antidepressant? Have you ever seen any brochures or patient information that was left in your department or your office from GSK?
>
> A. Not pertaining to Paxil.
>
> Q. But my question was from GSK, generally.

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[14] Although Dr. Durham is not a plaintiff, his reliance or non-reliance is important under New Jersey's learned intermediary doctrine. Under this doctrine, a manufacturer of prescription drugs satisfies its duty to warn by providing the prescribing physician with information regarding the drug's potential adverse effects. Spychala v. G.D. Searle & Co., 705 F. Supp. 1024, 1031 (D.N.J. 1988).

A. Yeah. We got a new cream called Altabax, yeah. It's an ointment for treatment of impetigo.

Q. And that's manufactured by GSK?

A. Yes.

* * *

Q. Now you mentioned earlier that you didn't have any brochures or pamplets regarding to Paxil specifically. Were you ever visited or met with a reprsentative from GSK regarding Paxil specifically?

A. No. I do not recall that, no.

Q. Are you aware whether or not GSK was aware of your prescribing Paxil to your patients?

A. I'm not aware of that. The reps I see for their topical products don't. I do not believe they handle Paxil. So, no, I'm not aware.

Q. Do you know if you've ever had any discussions with anyone that works for GSK regarding Paxil?

A. Not with any reps that come in the office. I've never made any phone call to GSK. I'm unaware of that.

(Id. at 75:9-77:4.)

Q. At the time you prescribed Paxil for Jake, did you know that Paxil had not been approved for use by pediatric patients by the FDA?

A. Yes.

Q. Knowing that, why did you prescribe Paxil for Jake?

* * *

A. Because I was comfortable with that medication. And I had good results in other pediatric patients with body dysmorphic disorder with it. I felt I had pretty darn good results when he came back in a month from it.

(Id. at 37:24-38:17.)

Reading such testimony cumulatively, Defendant asserts that since neither Plaintiffs nor

Dr. Durham experienced *any* promotion of Paxil, let alone off-label promotion, Plaintiffs cannot viably allege reliance.

Defendant's arguments, however, offer a myopic view of the record and misconstrue the relevant jurisprudence. It is well-established that a plaintiff need not hear the misrepresentation from the defendant directly for there to be actionable fraud: "where false representations are made to one person with the intent that they be communicated to others for the purpose of inducing the others to rely upon them, they may form the basis of an action for fraud by those others." Port Liberte, 924 A.2d at 601 (quoting Metric Inv., Inc. v. Patterson, 244 A.2d 311 (N.J. Super. Ct. App. Div. 1968)). Under this principle of "indirect reliance," although a plaintiff must actually hear and consider the misrepresentation, the communication of it may be by "means however attenuated." Brown ex rel. Estate of Brown v. Philip Morris Inc., 228 F. Supp. 2d 506, 519 (D.N.J. 2002) (quoting Kaufman v. i-Stat Corp., 754 A.2d 1188, 1197 (N.J. 2000)).

In Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995), abrogated on other grounds, 518 U.S. 470, 116 S. Ct. 2240 (1996), a heart valve recipient, who had the valve removed and replaced after learning of problems with it through both media sources and her doctor, brought an action against the manufacturer for negligent manufacture and design, strict products liability, breach of implied warranty of merchantability and fitness for particular purpose, breach of express warranty, and fraud. The Third Circuit recognized that the maker of a medical product who markets or promotes that product to a physician has reason to expect that patients and recipients of that product "would be affected by the information it published and distributed to doctors." Id. at 1335. Although there was no direct evidence that the prescribing doctors had read any specific promotional materials about the valve, the court noted that the facts of (1) the

nationwide distribution of the promotional materials and (2) the doctors' statements that they read standard journals in which the defendant's advertisements appeared in order to stay current with developments in their field, suggested that the defendant's promotional materials likely affected the doctors' choice to implant the heart valve in the plaintiff. Id. at 1336.

Similarly, in McDarby v. Merck & Co., Inc., 949 A.2d. 223 (N.J. Super Ct. App. Div. 2008), defendants appealed several evidentiary rulings made during the trial of a products liability action alleging inadequate warnings on the prescription drug Vioxx. In particular, defendant challenged the court's admission of evidence regarding its marketing practices that did not target plaintiffs or their physicians. Id. at 266. The court deemed the defendant's marketing practices to be relevant and, thus, admissible since the patient's treating physician testified that he read product literature, package inserts and "Dear Doctor" letters. Id. at 268-69. Further, the doctor testified that had he known of the risks of the drug, he would not have prescribed the drug. Id. at 269.

Reading the record in the light most favorable to Plaintiffs in this case, this Court also finds that they have made a sufficient showing of reliance to withstand summary judgment. First, Dr. Durham testified that he was, in fact, influenced by the medical community in his decision to prescribe Paxil.

> Q. How did you determine that Paxil was the right medication for Jake based on your diagnosis of body dysmorphic syndrome?
>
> A. First of all, the SSRIs in general are the ones recommended for the treatment of this disorder. I had ordered Paxil for several patients prior to this time. And the guru of psychocutaneous medicine happened to be my former partner. She wrote the book – Caroylyn Koblenzer, M.D. – on psychocutaneous medication. And so I have taken a real interest in these disorders in that dermatologists quite frequently deal with depressed,

> anxious, panic-attacky obsessive/compulsive patients. In fact, she wrote the whole book on the condition. And she was a frequent user of Paxil.

(Durham Dep. 59:24-60:18.)

Moreover, Dr. Durham testified that his prescribing practices were generally guided by information from many other sources. (Id. at 65:18-25.) Primarily, he indicated that he had seen Paxil advertisements in medical journals. (Id. at 75:9-13.) Further, he indicated as follows:

> Q. Doctor, do you know what the Physician Desk Reference is?
>
> A. Yes.
>
> Q. And what is it?
>
> A. It's a compendium of all medications, and it states their indication and their side effects and their interactions and their dosing and, you know, all the information pertaining to that medication.
>
> Q. Do you use the PDR to obtain information about medications?
>
> A. Daily. Well, several times a week, let's say.
>
> Q. And what information about medications do you find in the PDR?
>
> A. Frequently, with pediatric dosing – I mean, I know most of the medications, but now and then you need to find out a per-weight dosing of certain medications. And in this day and age drug interactions are frequently looked up. Of course, I see a lot of drug reactions, so I like to look up and see what's been reported for that medication.
>
> Q. Do you use the PDR to educate yourself on the risks and benefits of particular medications when you prescribe it?
>
> A. Yes, I have.
>
> Q. Do you use any other sources of information for your prescribing practices?
>
> A. Journals, conferences, tapes, lectures.

Q. Is that it?

A. Yes.

(Id. at 72:10-73:18.)

Finally, Dr. Durham stated that, in light of the black box warning currently on the Paxil label, he no longer prescribes the drug to adolescent patients:

Q. Now, you mentioned that you don't prescribe Paxil for pediatric patients, child or adolescents anymore. Why is that?

A. Well, the black box warning is such that I've been led to believe that people in the depths of depression and they get on an SSRI, perhaps it may give them enough energy to actually commit suicide.

(Id. at 59:16-23.)

Taken as a whole, such evidence creates a genuine issue of material fact as to whether Dr. Durham was influenced, albeit indirectly, by GSK's allegedly fraudulent or misleading promotion of Paxil as safe and effective for use in adolescents. Although the deposition testimony cited by Defendant reveals that Dr. Durham never directly received any promotional materials about Paxil in his office and never spoke with a GSK representative regarding Paxil, these statements far from equate to a showing that Dr. Durham did not rely on any of GSK's alleged misrepresentations about Paxil from *any other* sources. Indeed, Dr. Durham expressly indicated that he (a) relied on the knowledge of his former partner, who in turn may have considered Paxil promotional materials; (b) read journals, some of which contained Paxil advertisements; (c) attended lectures; and (d) read the Physicians Desk Reference. Any of these sources – not simply the brochures and GSK sales representative meetings referenced by Defendant – could have resulted in him relying upon, in some attenuated fashion, the substance

of GSK's alleged misrepresentation regarding Paxil. Nothing in the record supports Defendant's unsubstantiated suggestion that Dr. Durham relied solely on his own medical intuition about the safety and efficacy of the drug. Any challenges by Defendant to Dr. Durham's lack of specificity regarding the sources of his information about Paxil are ultimately questions for the jury.[15]

2. Claims of GSK's Off-Label Promotion of Paxil

In its next argument, Defendant contends that Plaintiffs' Complaint repeatedly accuses GSK of promoting off-label use of Paxil,[16] yet Plaintiffs have not identified any evidence of GSK's promotion of off-label pediatric use.[17] Moreover, Defendant asserts that Plaintiffs have

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[15] Defendant contends that Plaintiffs have not tied Dr. Durham's use of the PDR to his decision to prescribe Paxil to Jake Garrison. The Court notes, however, that Dr. Durham stated that he regularly used the PDR to prescribe dosing information. It is a basic rule of evidence that "[e]vidence of the habit of a person . . . whether corroborated or not and regardless of the presence of eyewitnesses, is relevant to prove that the conduct of the person . . . on a particular occasion was in conformity with the habit or routine practice." FED. R. EVID. 406.

Additionally, Defendant argues that the PDR itself, in the section discussing Paxil, contains the language that "[s]afety and effectiveness in the pediatric population have not been established." (Pls.' Ex. 35.) Even assuming, however, that such language can be deemed a warning, Plaintiffs have, as discussed later in this opinion, adduced evidence that GSK claimed that Paxil was safe and effective for use in adolescents. The New Jersey Superior Court has recognized that "if a product seller or manufacturer promotes, advertises or encourages in any manner or fashion a specific use of a product that it simultaneously warns against, these 'representations' may very well 'counteract' the effectiveness of the original warning, rendering it null and void." Koruba v. Am. Honda Motor Co., Inc., 935 A.2d 787, 793 (N.J. Super. Ct. App. Div. 2007), certif. denied, 944 A.2d 32 (N.J. 2008).

[16] For example, in paragraph 38(f) of the Complaint, Plaintiffs assert that GSK is liable for "[n]egligently and carelessly over promoting Paxil in a zealous and unreasonable way, even though Paxil was not approved for use with pediatric patients, without regard to the potential danger that it poses for pediatric patients." (Compl. ¶ 38(f)). In addition, in paragraph 68(g), Plaintiffs assert that GSK "[a]ggressively promoted Paxil to doctors for use with pediatric patients even though Paxil was not, and is not, approved for use with children and adolescents." (Compl. ¶ 68(g).)

[17] Notably, "a physician may prescribe a legal drug to serve any purpose that he or she deems appropriate, regardless of whether the drug has been approved for that use by the FDA."

not shown that any such promotion had any impact on Dr. Durham's decision to prescribe Paxil to Jake Garrison. In the absence of such evidence, Defendant argues that summary judgment must be granted with respect to any such allegations in the Complaint.

Such a contention fails on several grounds.[18] First, to the extent Defendant argues that Plaintiff cannot tie any off-label promotion of Paxil to Dr. Durham's decision to prescribe Paxil to Jake, the Court has already fully discussed and rejected that claim.

Second, Defendant's assertion that Plaintiff has produced no evidence of off-label promotion is unfounded. Indeed, Plaintiff has referenced several public representations by GSK or by researchers, seemingly connected with GSK,[19] which could possibly form the basis of the claimed "off-label" promotion. For example, in an October 1998 internal memorandum, GSK noted that only "[p]ostive data" from Study 329 would be presented at an upcoming conference in Paris. (Pls.' Ex. 18.) Further, a 1998 poster authored by thirteen psychiatrists entitled "Safety of paroxetine in the treatment of adolescent depression" was presented at the New Clinical Drug

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Washington Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2002). Such off-label use is commonplace in modern medical practice and unregulated by the FDA. Id. Nonetheless, a manufacturer cannot advertise or promote an off-label use of its drug. Id.

[18] Plaintiffs argue that they do not have an independent cause of action for off-label promotion and, as such, summary judgment on such allegations is improper. (Pls.' Mem. Opp. Mot. Summ. J. 14.) As discussed above, however, Plaintiffs' claims of off-label promotion are the sole remaining foundation of their fraud and negligent misrepresentation claims. It is thus incumbent on this Court to determine the legal validity of such claims.

[19] In its Reply Brief, Defendant argues that every single outside researcher involved in the pediatric studies that has been deposed by Plaintiffs' counsel testified that no one at GSK asked them to promote Paxil for pediatric use. (Def.'s Reply Br. 4 n.5 (citing Def's Opp. to Pls' Additional Statement of Facts ¶¶ 13-16.).) While Defendant's evidence certainly calls into question whether the alleged off-label promotion statements were actually prompted by GSK, it is not within this Court's province to resolve such factual disputes.

Evaluation Unit Annual Meeting in Boca Raton, and claimed that Study 329 demonstrated "the safety of paroxetine in the treatment of adolescent depression," and that any side effects were modest. (Pls.' Ex. 22.) On December 9, 1999, Karen Wagner, one of the clinical investigators of Study 329, spoke to Neuroscience Consultants and stated that Paxil was one of the few pharmaceuticals that had safety and efficacy data to support its use in the adolescent population. (Pls.' Ex. 24.) Between 1999 and 2001, Dr. Neal Ryan, another of the clinical investigators of Study 329, gave Power Point presentations to audiences of doctors stating that "Paroxetine [Paxil] is an effective treatment for MDD in adolescent outpatients" and "Safety: Paxil was well tolerated." (Pls.' Ex. 25.) In a July 2001 article published in the Journal for the American Academy of Child and Adolescent Psychiatry, GSK claimed that "Paroxetine was generally well tolerated in this adolescent population, and most adverse effects were not serious. The most common adverse effects reported during paroxetine therapy were headache, nausea, dizziness, dry mouth, and somnolence." (Pls.' Ex. 31.) Similarly, in an article entitled, "Adolescent Depression: Efficacy of Paroxetine," GSK affirmed that "Paroxetine provides effective treatment for major depression in adolescents."[20] (Pls.' Ex. 27.) Although Defendant refers to alternative evidence in an effort to rebut any showing of off-label promotion, such contrary evidence simply emphasizes the existence of a currently unresolvable jury question.[21]

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[20] Notably, in light of GSK's promotional activities, the State of New York filed a lawsuit against GSK for fraud, alleging an illegal campaign to promote Paxil for pediatric use. (Pls.' Ex. 66.) The case was settled in 2004 with GSK agreeing to post data regarding the safety and effectiveness of Paxil on its website. (Pls.' Ex. 67.)

[21] Defendant contends that Plaintiff's expert, Dr. Kapit, conceded that he could identify no documents referencing off-label promotion of Paxil and had no evidence of sales representatives promoting Paxil for off-label pediatric use. (Def.'s Mem. Supp. Mot. Summ. J. 9-10.) Aside from being nothing more than contrary evidence, however, Dr. Kapit actually

In short, the Court finds no basis for granting summary judgment on Plaintiffs' allegations of off-label promotion. A genuine issue of material fact exists as to whether GSK engaged in such promotion and whether Plaintiffs, through their physician Dr. Durham, relied on the statements made in such promotion. Accordingly, the Court denies summary judgment on this argument.

3. Breach of Express Warranty Claim

Defendant next contends that Plaintiffs' claim for breach of express warranty is deficient and cannot survive summary judgment. Again, the Court must reject this argument. [22]

Express warranties in New Jersey are governed by Article 2 of the state's Uniform Commercial Code. N.J. STAT. ANN. 12A:2-101 *et seq.* Section 2-313(1) of the Code recognizes express warranties that arise from, among other things:

> (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

Id.; Brady v. Rockwell Intern. Corp., Civ. A. No. 90-2321, 1993 WL 424238, at *4 (D.N.J. Oct. 14, 1993). The UCC makes clear that an express warranty is created when a seller makes a promise to a buyer related to a good or promises that a good will conform to a specific

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indicated that he may have seen evidence regarding sales representatives promoting pediatric use to a treating physician. (Def.'s Ex. 6, Richard Kapit Dep. ("Kapit Dep.") 368:16-25, Jan. 31, 2008.)

[22] Neither party disputes the fact that the claim for breach of express warranty is not subsumed by the PLA. Banner v. Hoffman-La Roche, Inc., 891 A.2d 1229, 1235 (N.J. Super. Ct. App. Div. 2006), certif. denied, 921 A.2d 447 (N.J. 2007).

description. Elias v. Ungar's Food Prods., Inc., ___ F.R.D. ___, 2008 WL 2704538, at *11 (D.N.J. Jan. 30, 2008). This express warranty provision makes clear that no formality or magic words are required to create an express warranty. Id. "The seller may be liable if its representation regarding the goods takes the form of newspaper, magazine, radio or television advertisements." Cipollone v. Liggett Group, Inc., 893 F.2d 541, 574-75 (3d Cir. 1990), aff'd in part, rev'd in part, 505 U.S. 404, 112 S. Ct. 2608 (1992). Further, a representation is presumed to be part of the basis of the bargain "once the buyer has become aware of the affirmation of fact or promise." Elias, 2008 WL 2704538, at *11 (quotations omitted).

"To establish a breach of an express warranty under N.J.S.A.12A:2-101, the plaintiff need not prove privity or traditional reliance." Id. Specifically, "[i]n New Jersey, privity is not required for plaintiffs to prevail against remote sellers in the chain of distribution." Arons v. Rite Aid Corp., No. 4641-03, 2005 WL 975462, at *22 (N.J. Super. Ct. Law. Div. Mar. 23, 2005). Under the Uniform Commercial Code, as construed by the New Jersey Supreme Court, "the absence of privity no longer bars a buyer from reaching through the chain of distribution to the manufacturer." Alloway v. Gen. Marine Indus., L.P., 695 A.2d 264, 275 (N.J. 1997). Further, "[a]s a rule, no proof of the buyer's reliance on the warranty is necessary other than that the seller's statements were of a kind which naturally would induce the purchase. The warranty need not be the sole inducement." Elias, 2008 WL 2704538, at *4 (quoting Bregman Screen & Lumber Co. v. Bechefsky, 83 A.2d 804 (N.J. Super. Ct. App. Div. 1951)).

In light of such principles, the Court cannot dismiss Plaintiffs' claim for breach of express warranty on summary judgment. As detailed above, Plaintiffs have produced sufficient evidence that GSK made various representations or affirmations of fact, within the meaning of

N.J.S.A. § 12A:2-313(a)(a), regarding the safety and efficacy of Paxil in children. These representations were made in various articles, conferences, and journals presented to the medical community. Plaintiffs further provide proof that Paxil did not conform with these representations, since pediatric use of Paxil has been directly linked with an increased risk of suicidality. Defendant's contrary arguments that none of the alleged statements were directed to either Plaintiffs or Dr. Durham, and that Dr. Durham did not rely on any statements, are of no avail. New Jersey law is clear that privity is not required; thus, statements made by GSK to Dr. Durham, and in turn to Plaintiffs, could constitute affirmations of fact upon which the bargain was made. Moreover, Plaintiffs' showing that Defendant's statements were of a kind which would naturally induce the purchase is sufficient to establish breach of express warranty; no particular reliance is necessary.[23] In short, a jury could conclude, from such evidence, that these various representations to Durham and communicated indirectly to Plaintiffs were the basis of the bargain for Plaintiffs' purchase and use of Paxil. Cipollone v. Liggett Group, Inc., 683 F. Supp. 1487, 1497 (D.N.J. 1988) (whether such affirmations, once made, are part of the bargain is a question of fact for the jury) (citing N.J. STAT. ANN. § 12:2-313(1)(a)).

4. Failure to Warn Claim Under the PLA

Defendant also challenges the viability of Plaintiffs' negligence and strict liability claims

[23] Defendants cite Parker v. Mowmedica Osteonics Corp., Civ. A. No. 07-2400, 2008 WL 141628, at *6 (D.N.J. Jan. 14, 2008) for the proposition that express warranty claims cannot stand where plaintiffs make only "bald assertions" that fail to provide a defendant with fair notice of the claim and the grounds on which it rests. Aside from the fact that Parker was decided on a motion to dismiss, this Court finds that Plaintiffs have given Defendant sufficient notice of the various representations forming the basis of the breach of express warranty claim.

alleging failure to warn[24] – both of which are subsumed by the PLA. Brown, 228 F. Supp. 2d at 516. Pursuant to the PLA,

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.

N.J. STAT. ANN. § 2A:58C-2. With respect to failure to warn claims, the PLA goes on to specifically state:

> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes

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[24] Plaintiffs' Complaint also contains a claim for "negligent pharmaco-vigilance." (Compl. ¶¶ 42-46.) Although this Court could find no New Jersey case referencing this cause of action, negligent pharmaco-vigilance "apparently refers to the on-going duty to continually monitor, test and analyze data regarding the safety, efficacy and prescribing practices of a pharmaceutical company." Stratford v. SmithKline Beecham Corp., Civ. A. No. 07-639, 2008 WL 2491965, at *6 (S.D. Ohio Jun. 17, 2008) (citing White v. Smithkline Beecham Corp., 538 F. Supp. 2d 1023, 1026 (W.D. Mich. 2008)). As Plaintiffs present no opposition to Defendant's motion for summary judgment on this count, judgment on Count II of the Complaint shall be granted in favor of Defendant.

> of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

Id. § 2A:58C-4.

In the case at bar, Plaintiffs claim that GSK knew, as early as 1994, that Paxil was being prescribed off-label to children and adolescents. Moreover, they assert that, as of 1998, GSK had evidence that Paxil increased the risk of suicidality in children. Yet, GSK failed to issue a warning regarding these risks and, instead, promoted Paxil for use in children and adolescents.

Defendant counters this claim with four arguments. First, it asserts that it had no duty to warn of off-label uses. Second, it contends that Plaintiffs cannot overcome New Jersey's rebuttable presumption of the adequacy of Paxil's labeling and warnings. Third, it argues that Plaintiffs have not produced sufficient evidence of causation. Finally, it claims that Plaintiffs may not rely on the direct-to-consumer advertising exception. The Court addresses each argument individually.

a. Duty to Warn of Off-Label Use

In its first challenge to Plaintiffs' failure to warn claim, Defendant argues that, as a matter of law, GSK had no duty to warn Dr. Durham regarding an off-label use of Paxil. The Court finds no merit to this argument.

"To prevail on a claim for failing to adequately warn, a plaintiff must establish that (1) the product did not contain an adequate warning; (2) the inadequacy in the warning existed when the product left the defendant's control; (3) the inadequate warning caused injury to the plaintiff; and (4) the plaintiff was a reasonably foreseeable user of the product." Perlman v. Virtua Health, Inc., Civ. A. No. 01-651, 2005 WL 1038953, at *3 (D.N.J. May 3, 2005). Under New Jersey

law, "the determination of the existence of duty is a question of fairness and public policy." Kuzmicz v. Ivy Hill Park Apartments, Inc., 688 A.2d 1018, 1020 (N.J. 1997).

Defendant bases its claim that it had no duty to warn on the Pennsylvania case of Davenport v. Medtronic, 302 F. Supp. 2d 419 (E.D. Pa. 2004). In Davenport, the plaintiff alleged that a manufacturing company was liable on a negligent manufacturing theory for allowing "bilateral implantation" of its medical device when the FDA had allowed only "unilateral implantation." Id. at 439. The court noted that such "off-label use 'is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine.'" Id. at 439-40 (quoting Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350, 121 S. Ct. 1012 (2001)). Citing to other similar cases from other states, the Court declined to hold the manufacturer of the medical device liable for allowing its off-label use.[25] Id. at 440.

This Court, however, remains unpersuaded by this jurisprudence. Davenport is a Pennsylvania case decided under Pennsylvania law and, thus, not indicative of New Jersey law on this matter. Another case from this Court has previously recognized that "[t]here are differences with respect to whether warnings are required for the off-label use of a drug." Blain v. Smithkline Beecham Corp., 240 F.R.D. 179, 194 (E.D. Pa. 2007). As noted in Blain,

> Some states require no warning, see Robak v. Abbott Labs., 797 F. Supp. 475, 476 (D. Md.1992), while others have varying levels of requirements for adequate warning of an off-label use. Miles Labs., Inc. v. Superior Court, 133 Cal. App. 3d 587, 184 Cal. Rptr. 98, 100 (1982) (manufacturer liable for failure to warn of risks of off-label uses of its product if the manufacturer knew or should have known of

[25] Defendant also cites Cox. v. Depuy Motech, Civ. A. No. 95-3848, 2000 WL 1160486, at *8-9 (S.D. Cal. Mar. 29, 2000) and Robax v Abbott Labs., 797 F. Supp. 475, 476 (D. Md. 1992).

> the off-label use and that use accounted for a significant portion of the manufacturer's sales of the drug); Peterson v. Parke Davis & Co., 705 P.2d 1001, 1003 (Colo. Ct. App. 1985); Reeder v. Hammond, 125 Mich. App. 223, 336 N.W.2d 3, 5-6 (1983) (intervening negligence of a physician precludes the manufacturer's liability for failure to warn of risks of off-label use).

Id. at 194-95.[26]

As a general rule, under New Jersey law, a manufacturer has a duty to warn of all known adverse effects of a drug as soon as reasonably feasible upon actual or constructive knowledge of the danger. Feldman v. Lederle Labs., 479 A.2d 374, 388-89 (N.J. 1984). "[A] manufacturer who knows or should have known of the danger of side effects of a product is not relieved of the duty to warn." Id. at 384. In addition, the New Jersey Supreme Court has explicitly recognized that "physicians have the right, exercising reasonable medical judgment, to use medical devices for off-label purposes that are not FDA approved, provided that the FDA has approved the device for some other purpose." Blazoski v. Cook, 787 A.2d 910, 920 (N.J. Super. Ct. App. Div. 2002). Synthesizing such principles, a patient prescribed an off-label use of a drug may be a reasonably foreseeable user of the product, such that a manufacturer has a duty to warn of all known adverse effects associated with such use. No New Jersey court has held, as Defendant now asks the Court to do, that New Jersey law exempts pharmaceutical companies that fail to warn of the

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[26] Cases from other federal courts applying state law have expressly found that a pharmaceutical manufacturer had a duty to warn of risks associated with off-label use. See, e.g., McNeil v. Wyeth, 462 F.3d 364, 370-71 (5th Cir. 2006) (under Texas law, plaintiffs can pursue failure to warn action despite off-label use of drug); Southern v. Pfizer, Inc., 471 F. Supp. 2d 1207, 1218 (N.D. Ala. 2006) (recognizing, under Alabama law, that the drug's manufacturer owed a duty to warn about the potential dangers of using prescription drug for an off-label to the patient's prescribing physician by the drug's manufacturer.); Woodbury v. Janssen Pharm., Inc., Civ. A. No. 93-7118, 1997 WL 201571, at *9 (N.D. Ill. Apr. 10, 1997) (recognizing, under Illinois law, that a pharmaceutical manufacturer has a duty to warn of any dangers associated with off-label use of their product if such dangers were reasonable known).

dangers of off-label uses of their drugs, despite having information of such dangers.

In this case, Plaintiffs do not contend that GSK is liable for allowing Dr. Durham to use Paxil in an off-label manner, nor do they claim that GSK had a duty to prevent such off-label use. Rather, they assert that GSK knew that Paxil was being used in children and adolescents,[27] knew of the increased risk of suicidality associated with that usage,[28] yet failed to provide adequate warnings. In light of New Jersey's requirement that a pharmaceutical manufacturer has a general obligation to warn of all known risks of the drugs as soon as reasonably feasible, the Court finds that Defendant maintains a duty to warn of off-label uses.[29]

b. Rebuttable Presumption of Adequacy

In a second effort to undermine Plaintiffs' failure to warn claim, Defendant argues that Plaintiffs cannot overcome the rebuttable presumption, under New Jersey law, that the instruction or warning is adequate. Specifically, under the New Jersey PLA,

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[27] The exhibits cited by Plaintiffs suggest that GSK was aware of widespread pediatric use of Paxil. For example, in a June 1994 marketing document, GSK stated, "Other psychs have indicated that a liquid form of Paxil would be very convenient for their geriatric patients and children." (Pls.' Ex. 4.) Additionally, a September 1, 1997, e-mail from GSK employee Stella Jones to Thomas Kline in GSK's regulatory affairs department, stated that GSK wanted to "move forward with the pediatric sNDA [supplemental new drug application] with Paxil as soon as possible even if Prozac and Zoloft may be ahead of us given FDA's keen interests in those two drugs due to the widespread use in this patient population." (Pls.' Ex. 13.)

[28] As this Court noted in our previous opinion in this case, Plaintiffs have presented sufficient evidence that GSK knew of the risks associated with pediatric use of Paxil as early as 1998. Knipe v. SmithKline Beecham, Corp., Civ. A. No. 06-3024, 2008 WL 4090995, at *21 (E.D. Pa. Aug. 28, 2008).

[29] Even the FDA regulations, in theory, impose a duty to warn of off-label uses. See 21 C.F.R. § 201.128 ("if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes or uses other than the one for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.").

> If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate.

N.J. STAT. ANN. § 2A:58C-4. Defendant now contends that, at all times before Jake Garrison's death, it provided FDA-approved warnings for Paxil. Accordingly, it claims that the Paxil label is subject to the presumption of adequacy.

The New Jersey Supreme Court has explained that "when prescription drugs are marketed and labeled in accordance with FDA specifications, the pharmaceutical manufacturers should not have to confront state tort liability premised on theories of design defect or warning inadequacy." Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1257 (N.J. 1999) (internal quotations omitted). Thus, "[a]ny duty to warn physicians about prescription drug dangers is presumptively met by compliance with federal labeling." Id. at 1259.

This presumption is not absolute. Id. The New Jersey Supreme Court expressly held that "[f]or all practical purposes" it may be overcome only in the case of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects." Id. More recently, the New Jersey Superior Court recognized that other types of conduct could also warrant overcoming this presumption. McDarby v. Merck, 949 A.2d 223, 256 (N.J. Super. Ct. App. Div. 2008). In that latter case, two patients brought claims, under the PLA, against the manufacturer of a drug used to treat acute pain and arthritis, alleging defendant's inadequate warning of cardiovascular risks. Id. at 229. The evidence revealed that, at the time of the initial approval of the new drug application, defendant was aware of a possible, but unconfirmed risk of increased cardiovascular

events. Id. at 259. Although the FDA officer urged further testing, it was not immediately done. Id. Instead, the defendant focused its post-FDA approval attention on completion of a large-scale blinded study of persons with rheumatoid arthritis (the "VIGOR" study), in an effort to expand the marketing for its product. Id. This study unintentionally confirmed the increased cardiovascular risks inherent in the drug's use. Id. When seeking approval of a new indication for its drug, however, the defendant "sought to dilute the labeling required as a result of [its] VIGOR study" and "engaged in strenuous efforts to ensure that the results of the VIGOR study were not communicated to prescribing physicians by sales persons." Id. When the FDA was finally made aware of definitive evidence of increased risks, it took over two years for the labeling changes to occur. Id. The defendant argued that because the FDA had approved both an initial and a supplemental label for the drug, New Jersey's presumption of adequacy applied. Id. at 256.

The New Jersey Superior Court rejected the Perez court's limitation of bases for rebuttal of the presumption of adequacy, as follows:

> In concluding that a hitherto unrecognized legal basis for an award of compensatory damages under the PLA exists here, we note that close scrutiny of the FDA and its regulatory power in a labeling context commenced only after *Perez* was decided, and that scrutiny disclosed flaws in the regulatory system, existing at least until the time of the 2007 Amendments, that render the dictum of *Perez* less all-encompassing than it might then have appeared. Commentators and courts have since recognized that, whereas pre-market approvals of drugs are generally thorough in nature, the ability of the FDA, post-market, "to detect unforeseen adverse effects of [a] drug and to take prompt and effective remedial action" is considerably less. . . . It is these flaws in that post-marketing oversight process that provide the foundation for the further exception to the presumption of adequacy that we find applicable to this case.

Id. at 256-57 (quoting Kessler & Vladeck, "A Critical Examination of the FDA's efforts to

Preempt Failure-to-Warn Claims," 96 GEO. L.J. 461, 466 (2008)). The court remarked that "[g]iven these admitted flaws in the FDA's control over postmarket labeling in the years that Vioxx was on the market, we are unwilling to accept Merck's position that the presumption of adequacy of a prescription drug's label can be overcome only upon proof of deliberate concealment or nondisclosure." Id. at 258. It concluded that, "[t]he fact that the label was finally revised in April 2002 to reflect . . . [information] known to Merck at least by March 9, 2000, . . . provides powerful evidence that the label approved in May 1999, which contained no precautions or warnings regarding cardiovascular risks, was inadequate, at least from March 9, 2000 onward." Id. at 259-60. Ultimately, the court deemed such evidence sufficient for a jury to conclude that the presumption of adequacy had indeed been rebutted.[30] Id. at 260.

In the case at bar, this Court declines to find the presumption of adequacy conclusively applicable for substantially the same reasons that we found, in our previous opinion, that the FDA had not preempted Plaintiffs' state law claims. First, as noted above, the New Jersey presumption requires that the warning at issue have been approved or prescribed by the FDA. N.J. STAT. ANN. § 2A:58C-4. "Off-label uses of approved medications have not been subjected to the baseline FDA scrutiny." In re Zyprexa Prods. Liab. Litig., Nos. 04-MD-1596, 05-CV-4115, 05-CV-2948, 06-CV-0021, 06-CV-6322, 2008 WL 2696916, at *43 (E.D.N.Y. Jul 2,

[30] Defendant suggests that Plaintiffs' emphasis on McDarby is misplaced and that, under Perez, 734 A.2d 1245 and Rowe v. Hoffman-La Roche, Inc., 917 A.2d 767, 774 (N.J. 2007), the presumption of adequacy can be overcome only on proof of deliberate concealment or nondisclosure. Neither Perez nor Rowe, foreclose the holding reached in McDarby. In fact, the McDarby court remarked that "[f]acts unavailable to the Supreme Court at the time of the Perez decision demonstrate that such a restriction [on ways to rebut the presumption] is too narrow." McDarby, 949 A.2d at 258. Moreover, Defendant's attempts to undermine McDarby are suspect in light of its later reliance on the case with respect to the issue of punitive damages.

2008). As discussed extensively in this Court's previous opinion, Knipe v. SmithKline Beecham, Civ. A. No. 06-3024, 2008 WL 4090995 (E.D. Pa. Aug. 28, 2008), prior to Jake Garrison's suicide in 2002, the FDA never considered any pediatric warnings with which Defendant could have been in compliance and, to date, has never approved Paxil for pediatric use:

> During the relevant period in this case, Paxil was not – and to date has not been - approved for pediatric use. As of the original approval in 1992, no evidence exists that the FDA received any pediatric clinical studies from any of the major SSRI manufacturers. In late 2001, the FDA first began receiving controlled studies of the seven major SSRI's in pediatric patients for the treatment of Major Depressive Disorder. Kallas Amicus Brief 13. On September 30, 2002, although the FDA had yet to affirmatively link increased suicidality in adolescents to Paxil, it declined to approve Zoloft, another SSRI, for treatment of pediatric Major Depressive Disorder, on the grounds that it could not prove efficacy. . . . At no point did the FDA deem the proposed pediatric warning scientifically unsubstantiated.

Id. at *21.[31] Defendant cites to no law – nor can this Court find any case – that applies the New Jersey presumption of adequacy to use of a drug in an unapproved population. More importantly, it is contrary to all reasonable logic to adopt Defendant's suggestion that it may hide behind an FDA-approved warning regarding adult use of Paxil, when the FDA never had the opportunity, during the pertinent period, to review the propriety of a proposed warning with respect to pediatric use of Paxil.

Moreover, as set forth in the prior decision, sufficient evidence exists upon which a jury could find that the warning was not adequate, thus rebutting any presumption that might apply:

> Prior to April of 2002, GSK had never submitted any pediatric clinical trial data to

[31] Defendant's reliance on Colacicco v. Apotex, Inc. was similarly addressed in detail in Knipe, 2008 WL 4090995, at *13-15.

the FDA.[32] It remains undisputed, however, that, as of 1998, GSK had completed Studies 329 and 377, both of which were the first two placebo controlled clinical trials of Paxil in children and adolescents. (PSUF ¶ 5, Ex. 5; ¶ 8, Ex. 14; ¶ 12, Ex. 21.) On July 30, 2001, GSK also issued the Final Clinical Report on Study 701, which was designed to evaluate the efficacy of Paxil in pediatric patients with major depressive disorder. (Id. ¶ 18, Ex. 30.) The first time GSK sought approval for pediatric indication of Paxil was on April 11, 2002, at which time it first submitted the results of the three studies. (Id. ¶ 26, Exs. 36, 37.) This submission, by all accounts, was the catalyst for a series of events culminating in the FDA required "black box" warning.

On October 7, 2002, Dr. Andrew Mosholder, the FDA reviewer of the pediatric Supplemental NDA for Paxil completed his review and noted an increase in "behavioral effects" coded "with terms such as hostility and emotional lability" which was "potentially confusing." (Id. ¶ 29, Ex. 39 at 6.) Accordingly, on October 21, 2002, the FDA requested from GSK clarification of the data regarding behavioral adverse events, as well as GSK's "rationale for coding suicide attempts and other forms of self-injurious behavior under the . . . term 'emotional lability.'" (Id. ¶ 30, Ex. 40.) Seven months later, GSK responded to this request and submitted a report that "suggested an increased risk (Paxil v. placebo) of various thoughts and behaviors coded as events considered 'possibly suicide related' and also for the subgroup of events that met [GlasxoSmithKline's] criteria for representing 'suicide attempts.'" Kallas Amicus Brief 17 (citing January 2004 Laughren Memo at 7). In an e-mail from Dr. Russell Katz of the FDA to Dr. Andrew Mosholder, dated June 2, 2003, Dr. Katz noted that almost all of the events previously subsumed under the term "Emotional Lability" in GSK's initial Supplemental NDA, "related to suicidality." (PSUF ¶ 41, Ex. 47.) He stated that the FDA was "planning to look at the NDAs for the other SSRIs to see whether or not similar events are being hidden by various inappropriate coding maneuvers. . . ." (Id. ¶ 42, Ex. 47.) The FDA then issued a Talk Paper on June 19, 2003 "recommending that Paxil not be used in children and adolescents for the treatment of MDD." (Id. ¶ 49, Ex. 51.) The FDA thereafter expanded its "investigation of a possible more general link between use of antidepressants in children" by requesting data similar to that submitted by GSK from the manufacturers of the eight other major anti-depressant drugs that had been studied in children. Kallas Amicus Brief 17. The FDA continued to study the issue

[32] Defendant contends that results from Study 377 were presented at the American Academy of Child and Adolescent Psychiatry (AACAP) Annual Meeting in Chicago in October of 1999, and numerous published articles reference the results of Study 329 and 377. (Def.'s Opp.Def's to Pls' Additional Statement of Facts ¶ 9.) Such evidence, however, does not establish that the full and complete data from those two Studies was ever provided to the FDA before GSK's submission of its supplemental NDA in April of 2002.

> extensively. (PSUF ¶ 59, Ex. 6.) Following the recommendations of an advisory committee, the FDA, on October 15, 2004, issued a Public Health Advisory and letter directing all manufacturers of SSRIs to add a "black box" warning and expanded warning statements to the labeling of all antidepressant medications describing the increased risk of suicidality in children and adolescents. (Id. ¶ 72, Ex. 74.)

Id. at *21 (footnote added).

Viewed in the light most favorable to Plaintiffs, such evidence, if true, could easily rebut the presumption of adequacy under the PLA. As recognized in McDarby, the FDA's inability to effectively regulate any post-market unforeseen adverse effects of the drug and take prompt and effective remedial action provides grounds for rebuttal in this case, where no pediatric indication was sought until after initial approval of the drug. Moreover, the fact that, when given the crucial data, the FDA finally required Defendant to revise its label in October 2004, to reflect what Defendant possibly knew as of 1998, "provides powerful evidence" that the label originally approved by the FDA, which contained no precautions or warnings regarding pediatric use, was inadequate, at least from 1998 forward. McDarby, 949 A.2d at 259-60.

In an effort to sidestep this potential rebuttal, Defendant contends that Plaintiffs' arguments are essentially "fraud-on-the-FDA" claims alleging that GSK's alleged withholding of data from or manipulation of studies provided to the FDA worked an actual fraud. Such claims, according to Defendant, are preempted by Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012 (2001), since "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the [FDA], and . . . this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objections." Id. at 348; see also Colacicco v. Apotex, 521 F.3d 253, 272 (3d Cir. 2008) (confirming that any argument that a pharmaceutical company

manipulated or withheld information from the DA borders on a fraud on the FDA claim and is, therefore, preempted).

This argument relies on a fundamental misunderstanding of the nature of a fraud on the FDA claim. The Buckman court defined fraud on the FDA claims as violations of the FDA disclosure requirements, which are "various provisions aimed at detecting, deterring and punishing false statements made *during the approval process*." Buckman, 531 U.S. at 349. (emphasis added). In order to secure FDA approval for a drug or medical device, "a manufacturer must demonstrate that its product is safe and effective for each of its intended uses." Washington Legal Found. v. Henney, 202 F.3d 331, 332 (D.C. Cir. 2000) (citing 21 U.S.C. § 355(d)). Once a drug is approved for particular indications, the FDA does not regulate off-label use of drugs unless the manufacturer engages in "direct advertising or explicit promotion" of such use. Id. at 333. The FDA has no authority to compel the submission of additional clinical information and, "[a]lthough drug companies are under a continuing obligation to report serious adverse events, with required safety reports to be filed every three months during the first few years of marketing of a drug, the FDA's adverse event reporting system is largely voluntary." In re Zyprexa Prod. Liab. Litig., ___ F. Supp. 2d ___ 2008 WL 4097408, at *47 (E.D.N.Y. Sep. 5, 2008). The FDCA also expressly states that "[n]othing in this chapter [including the disclosure requirements] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (1994 ed., Supp. V); see also Smith, Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and

Cosmetic Act, 55 FOOD & DRUG L.J. 245, 251-252 (2000) ("[f]ederal regulation of medical products is grounded in the introduction of devices in interstate commerce for commercial distribution, not use by physicians. This concept forms the basis for the 'practice of medicine' doctrine, which maintains that FDA lacks authority under the FDCA to regulate patient treatment decisions made by licensed physicians.").

As repeatedly emphasized, Defendant, in this case, never sought approval of a pediatric indication from the FDA until April of 2002, just before Jake Garrison's suicide. During the initial approval of Paxil, the FDA asked GSK to "[p]lease consider conducting post-approval studies with [Paxil] in depressed children and adolescents . . . [since] it is likely that [Paxil] will be used in children and adolescents, despite the absence of any relevant data," (Arning Decl. ¶ 28, Ex. 5), but neither mandated the completion and submission of such studies nor sanctioned GSK for failing to provide them. Indeed, the FDA had no involvement in reviewing studies of pediatric use of Paxil until the filing of GSK's supplemental NDA. Thus, Defendant's failure to provide data from its pediatric clinical studies prior to that time does not constitute a fraud on the FDA during the approval process. In turn, Plaintiffs' allegations of nondisclosure have no federal underpinnings that could be preempted by Buckman's holding.[33]

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[33] Plaintiff relies on the case of Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir. 2007), cert denied, 128 S. Ct. 1168 (2008). In that case, the Second Circuit interpreted a Michigan statute wherein a drug manufacturer enjoyed "an absolute defense" from such product liability suits if: (1) the FDA approved the safety and efficacy of the drug and (2) the drug and the labeling were in compliance with the FDA's approval at the time the drug left control of the manufacturer, unless the manufacturer,

> [i]ntentionally withholds or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug and cosmetic act and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

Finally, the Court takes note of the inherent hypocrisy in Defendant's argument. On one hand, Defendant contends that it had no duty to warn of known risks involved in off-label usage of the drug, whether or not it had reason to know of such off-label uses. On the other hand, it contends that once its drug was approved by the FDA for some indications, it was protected by the presumption of adequacy for FDA warnings for usage in all indications, even where the FDA had never considered the propriety of the warning. On a hypothetical third hand, it claims that any attempt to rebut the presumption by proof of nondisclosure is preempted by federal law, thereby making the presumption effectively unrebuttable. Applying such logic, a pharmaceutical

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Id. at 87-88 (quoting MICH. COMP. LAWS § 2946(5)(a)). The court declined to find that the exception required a showing of fraud-on-the-FDA, which was preempted by Buckman. Id. at 96. It noted that, "[f]inding preemption of traditional common law claims where fraud is not even a required element - but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law - would result in preemption of a scope that would go far beyond anything that has been applied in the past." Id. It went on to conclude that, "[u]ntil and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect." Id.

Defendant contests any reliance on Desiano based on the prior case of Garcia v. Wyeth Ayerst Labs., 385 F.3d 961, 966 (6th Cir. 2004). In Garcia, the Sixth Circuit, interpreting the same Michigan statute discussed by Desiano, found that Buckman prohibited a plaintiff from invoking the exceptions on the basis of a state court finding of fraud on the FDA because, "[s]uch a state court proceeding would raise the same inter-branch-meddling concerns that animated Buckman." Id. at 966. Defendant argues that because the Sixth Circuit sits in Michigan and was interpreting a Michigan statute, that case should control.

The Court need not resolve this dispute. Unlike the Michigan statute which gave manufacturers "absolute liability" absent a showing of fraud on the FDA, the New Jersey statute merely creates a presumption, which is not absolute and which may be rebutted in various circumstances. Further, the Michigan exception required a showing of nondisclosure of information required to be disclosed to the FDA by federal statute, thereby expressly adopting the fraud on the FDA standard. New Jersey case law demands only a showing of nondisclosure of after-acquired knowledge of harmful effects, regardless of whether such nondisclosure constitutes fraud on the FDA. Finally, as discussed above, the New Jersey presumption may be rebutted by other unique circumstances, such as in this case where there could have been no compliance with FDA labeling regarding pediatric usage, since such usage was never approved by the FDA.

manufacturer possessing information regarding hazards associated with off-label use of its drug would never have to warn the medical community of any off-label usage dangers or submit data regarding these dangers to the FDA. Such a result is contrary to New Jersey's "strong interest in encouraging the manufacture and distribution of safe products for the public and, conversely, in deterring the manufacture and distribution of unsafe products within the state," a policy that is "furthered through the recognition of claims and the imposition of liability based on principles of strict products liability law." Gantes v. Kason Corp., 679 A.2d 106, 111-12 (N.J. 1996). Accordingly, the Court declines to grant summary judgment on the basis of New Jersey's presumption of adequacy.[34]

c. Causation

Defendant also contends that, assuming that the presumption does not apply, the warning provided by GSK was nevertheless adequate on two grounds. First, it claims that Dr. Durham provided Mrs. Knipe with a warning regarding suicidal ideation inherent in body dysmorphic disorder and told her to watch out for "[w]orsening in depression, further withdrawal, you know, not sleeping, hostile behavior." (Durham Dep. 25:5-26:21.) Second, Defendant asserts that because Plaintiffs allowed Jake to take Accutane, even after being informed of its connection

[34] The other cases cited by Defendant in further support of the presumption are inapposite. In Dobrovic v. Friedman, 2006 WL 2355136, at *8 (N.J. Super. Ct. App. Div. Aug. 16, 2006), the defendant warned of the very side effect that the plaintiff experienced and the FDA had specifically considered and approved that precise warning. Likewise, in Abramowitz v. Cephalon, Inc., 2006 WL 560639, at *3 (N.J. Super. Ct. Law Div. Mar. 3, 2006), certif. denied, 917 A.2d 789 (N.J. 2007), it was undisputed that the FDA approved label contained a warning regarding the precise adverse condition suffered by plaintiff as a result of taking the drug. In this case, neither party disputes that the label for Paxil did not contain any warning regarding increased suicidality in pediatric users resulting from use of the drug. Moreover, this Court has repeatedly found that the FDA never considered the propriety of such a warning.

with suicidality, Plaintiffs cannot genuinely allege that they would not have allowed Jake to take Paxil if they had known about its alleged association with suicidality.

Causation is a fundamental requisite for establishing any product-liability action. The plaintiff must demonstrate product-defect causation, *i.e.* that the defect in the product was a proximate cause of the injury. D'Allesandro v. Bugler Tobacco Co., Civ. A. No. 05-5051, 2006 WL 3677854, at *3 (N.J. Dec. 7, 2006). When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his harm. Id.

The Court quickly dismisses Defendant's first attempt to show lack of causation. As convincingly argued by Plaintiffs, "[t]he fact that depression or body dysmorphic syndrome are associated with suicidal behavior and that his parents needed to monitor him is not the issue relative to this 'failure to warn' claim. Rather, the crux of this claim is that GSK neglected to warn Dr. Durham that Paxil (the very same medication that physicians were prescribing to treat depression and body d[y]smorphic syndrome in children) had the negative effect of actually increasing a child's suicidal behavior." (Pl. Mem. Opp. Mot. Summ. J. 23.) The absence of a warning to Plaintiffs or Dr. Durham about the risks of Paxil logically could have resulted in Plaintiffs' failure to exercise the appropriate degree of caution with respect to Jake's increased suicidal tendencies.

As to the second argument, the New Jersey Supreme Court has adopted a presumption that a plaintiff would have "heeded" an adequate warning if it had been given. D'Alessandro, 2006 WL 3677854, at *3 (citing Coffman v. Keene Corp., 628 A.2d 710 (N.J. 1983)). In this case, Dr. Durham testified that he no longer prescribes Paxil for pediatric patients as a direct

result of the black box warning. (Durham Dep. 57:16-23.) A logical extension of that testimony is that, had Dr. Durham had such a warning prior to 2002, he would have not prescribed Paxil to Jake. Moreover, Mrs. Knipe testified that with Accutane, the warnings were crystal clear, that she knew what signs of suicidality to look for while Jake was taking the medication and that she heeded those warnings. (Knipe Dep. 122:16-124:16.) As she was not given the same warnings with Paxil, she did not know to take the same precautions. (Id. 124:17-131:1.) Such testimony is more than sufficient to survive summary judgment on the issue of causation.

d. Direct-to-Consumer Exception

Defendant's final challenge to the failure to warn claim contends that Plaintiff cannot rely on the direct-to-consumer ("DTC") advertising exception established by the New Jersey Supreme Court in Perez, 734 A.2d at 1256. In Perez, the court recognized that a pharmaceutical manufacturer generally had no duty to directly warn the consumer under the learned intermediary doctrine, which allows a drug manufacturer to discharge its duties by supplying warnings to the patient's physician. Id. It concluded, however, that the learned intermediary doctrine does not apply to "the direct marketing of drugs to consumers" where the consumers alleged that they were influenced by the advertising campaign for the drug. Id. at 1256-57. Defendants now argue that because Plaintiffs have testified that neither Jake nor his family saw the advertisements for Paxil, the exception cannot apply.

In the case at bar, Plaintiffs disclaim any intent to rely on the DTC exception since they have established causation through the learned intermediary doctrine. Therefore, the Court

dismisses this argument by Defendant.[35]

5. Punitive Damages

The final point of contention between the parties concerns Plaintiffs' request for punitive damages. Defendant claims that punitive damages are not available for any of the claims falling within the PLA, nor are they available for the breach of express warranty claim. Accordingly, it seeks dismissal of this count.

The parties first dispute the law applicable to the punitive damages claim. Plaintiffs argue that, even if New Jersey law applies to the substantive claims, Pennsylvania law should apply to their claim for punitive damages under the principle of *depecage*. Under *depecage*, "different states' laws may apply to different issues in a single case." Taylor v. Mooney Aircraft Corp., 265 Fed. Appx. 87, 91 (3d Cir. 2008). Pennsylvania's choice of law analysis employs *depecage*. Id. (citing Berg Chilling Sys., Inc. v. Hull Corp., 435 F.3d 458, 462 (3d Cir. 2006)). Similarly, *depecage* is explicitly endorsed in comment (d) to Section 145 of the Restatment (Second) of Conflict of Laws, which states that "courts have long recognized that they are not bound to decide all issues under the local law of a single states, but instead each issue is to receive separate consideration if it is one which would be resolved differently under the local law rule of two or more of the potentially interested states." REST. (SECOND) OF CONFLICT OF LAWS § 145, cmt. d.

Applying Pennsylvania's choice of law analysis, the Court finds that a real conflict exists

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[35] In its reply brief, however, Defendant contends that Plaintiffs Complaint asserted that GSK owed a duty to warn the "consuming public." (Def.'s Reply Br. 17-18 n.17 (quoting Compl. ¶ 34.).) The Court notes that this allegation is made as part of a general background statement in the Complaint and is not part of any of Plaintiffs' causes of action.

between the laws of Pennsylvania and New Jersey. The Pennsylvania Supreme Court has not foreclosed the awarding of punitive damages in a strict liability action if the facts warrant such an award. North Side Foods Corp. v. Bag-Pack, Inc., Civ. A. No. 06-1612, 2007 WL 954106, at *4 (W.D. Pa. Mar. 28, 2007). An award of punitive damages is appropriate where the defendant's actions are so outrageous that they "demonstrate intentional, willful, wanton or reckless conduct." SHV Coal, Inc. v. Cont'l Grain Co., 587 A.2d 702, 704 (Pa. 1991). Where a defendant acts with an evil motive or a reckless indifference to the rights of others, punitive damages may be awarded. Feld v. Merriam, 485 A.2d 742,747 (Pa. 1984) (citing RESTATEMENT (SECOND) OF TORTS § 908(2)).

In New Jersey, section five of the New Jersey Products Liability Act provides:

> Punitive damages may be awarded to the claimant only if the claimant proves, by a preponderance of the evidence, that the harm suffered was the result of the product manufacturer's or seller's acts or omissions, and such acts or omissions were actuated by actual malice or accompanied by a wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by the product. For the purposes of the section "actual malice" means an intentional wrongdoing in the sense of an evil-minded act, and "wanton and willful disregard" means a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences or such action or omission. Punitive damages shall not be awarded in the absence of an award of compensatory damages.

N.J. STAT. ANN. 2A:58C-5(a). In McDarby v. Merck & Co., 949 A.2d 223 (N.J. Super. Ct. App. Div. 2008), however, the New Jersey Superior Court expressly found that a claim for punitive damages in a products liability action under the New Jersey PLA, which relies upon an allegation of fraud on the FDA for proof of intentional wrongdoing or willful disregard, is preempted by Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012 (2001). Id. at 276.

Given such a real conflict, and the fact that each state's interests would be impaired by

application of the other state's law, the Court must then analyze the contacts of each state. Hammersmith v. TIG Ins. Co., 480 F.3d 220, 231 (3d Cir. 2007). In Kukoly v. World Factory, Inc., Civ. A. No. 07-1644, 2007 WL 1816476, at *2 (E.D. Pa. June 22, 2007), the Court considered the law applicable to a punitive damages claim in a products liability action where a true conflict existed between the states' laws. It noted that the defective product was distributed and sold in Pennsylvania, the injury occurred in Pennsylvania, the plaintiffs were domiciled in Pennsylvania, and the defendant placed its products into the stream of commerce where it was reasonably foreseeable the products would end up in Pennsylvania. Id. at *3. Plaintiffs did not travel to the defendant company's home state of Texas and, instead, purchased the allegedly defective product in a Wal-Mart store in Pennsylvania. The facts were unclear whether the injurious conduct occurred in China (from where the products were imported), at one of the five Wal-Mart distribution centers, or at the local Wal-Mart in Pennsylvania. Accordingly, the Court applied Pennsylvania law. Id.

This Court is similarly persuaded that New Jersey law must apply. Although Defendant is domiciled in Pennsylvania and likely made several of the decisions regarding the study and marketing of Paxil in Pennsylvania, the majority of crucial contacts occurred in New Jersey. Any marketing relevant to this case was directed to a New Jersey market. Jake Garrison was prescribed Paxil by a New Jersey physician, Plaintiffs purchased Paxil in a New Jersey pharmacy and Jake Garrison ultimately suffered all side effects in New Jersey.

Moreover, the Court is mindful that New Jersey has sought to comprehensively regulate products liability actions in its state through the PLA and that the PLA applies to all of the substantive claims in this action. Although this Court could technically apply one state's law

with respect to liability and compensatory damages and another state's law with respect to punitive damages, we recognize the inherent problem in doing so. "Indeed, mixing and matching the laws of different states in one case can readily lead to a result 'that neither state would allow . . . [since when] a court combines elements of the laws of different states it may upset the delicate balance achieved by legislative compromise.'" Petrokehagias v. Sky Climber, Civ. A. Nos. 96-6965, 97-3889, 1998 WL 227236, at *8 (E.D. Pa. 1998) (quoting Schulhoff v. Northeast Cellulose, Inc., 545 F. Supp. 1200, 1207-08 (D. Mass. 1982)). As applying the same law to liability, compensatory damages and punitive damages in this case "serves the administrative interest of not creating undue confusion," the Court declines Plaintiffs' request for *depecage*. Id.[36]

Having concluded that New Jersey law applies to Plaintiffs' claim for punitive damages, this Court must examine whether such claim can survive summary judgment review under recent New Jersey jurisprudence. As noted above, in McDarby, defendant Merck submitted a new drug application to the FDA for its drug Vioxx. 949 A.2d at 231. The FDA approved the initial drug application, despite the existence of a possible linkage with cardiovascular risks. Id. at 259. Merck then completed a new study, which inadvertently confirmed those risks. Id. Although Merck submitted a supplemental new drug application with the results of the study, it attempted to disguise the severity of the cardiovascular adverse experiences associated with the drug. Id. At trial, the plaintiff received punitive damages on the grounds that if the complete study analysis

[36] Plaintiffs cite to Kelly v. Ford Motor Co., 933 F. Supp. 465 (E.D. Pa. 1996) in support of its argument that *depecage* should apply to allow a conflict of laws analysis with respect to a punitive damages claim. This case, however, is distinguishable in light of the fact that the court dealt with a motion for partial summary judgment solely on the claim for punitive damages. The court did not discuss *depecage*.

had been furnished by Merck to the FDA, the FDA may have either not approved or responded in a different fashion to Merck's supplemental new drug application. Id. at 271-72. Although the court did not find the failure to warn claim itself preempted, it determined that the basis for the punitive damages claim was a fraud on the FDA allegation that fell within the precise contours of Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012 (2001). Id. at 275-76. Ultimately, the New Jersey Superior Court held that "[b]ecause the punitive damages provisions of N.J.S.A. 2A:58C-5c impinge upon federal statute and regulation to the same extent that was recognized in Buckman, 531 U.S. at 349, 121 S.Ct. at 1017-18, we find the principles of implied preemption applied by the Court in Buckman to be applicable here." McDarby, 949 A.2d at 276.

To the extent that Plaintiffs rest their claim for punitive damages on the allegation that GSK "manipulated the data" it submitted to the FDA in support of its supplemental NDA seeking approval of a pediatric indication for Paxil, this claim clearly falls within the bounds of McDarby. Any allegation that Defendant failed to submit or hid crucial data during an FDA approval process effectively invokes a fraud on the FDA claim. In turn, such a claim is impliedly preempted.[37]

Such a finding, however, does not automatically foreclose a punitive damage award, as Plaintiffs offer two other bases to support their claim. First, they assert that "motivated by monetary greed and the multi-million dollar annual profits, GSK marketed and sold a product

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[37] Plaintiffs argue that McDarby was wrongly decided. They contend that this Court should instead follow the Second Circuit's reasoning in Desiano, supra, which interpreted a Michigan statute and found that Buckman was limited to a specific cause of action premised on fraud on the FDA and did not apply to a common law claim that required a finding of fraud on the FDA to overcome a statutory immunity. 467 F.3d at 92-93. As Desiano concerned a Michigan statute, however, and as this Court is concerned with New Jersey's interpretation of its own law, the Court rejects this argument.

without any warnings concerning the risk of suicidal behavior despite clear, statistically significant clinical trial results showing that Paxil-treated adolescent patients engaged in suicidal behavior four times the rate that placebo treated patients did" and hid the data from the medical community. (Pls.' Mem. Opp. Mot. Summ. J. 26.) Second, they allege that "[a]side from concealing the negative data, GSK actually promoted Paxil for treating pediatric/adolescent conditions, such as depression, by falsely claiming that Paxil was safe and effective." (Id. at 27.)

The Court declines to find that McDarby's prohibition on punitive damages extends to such assertions. As outlined in detail above, fraud on the FDA requires some type of fraud during the approval process for the intended use of the drug. Plaintiff's first two bases for punitive damages do not, in any way, suggest that GSK fraudulently induced the FDA to approve Paxil. As repeatedly emphasized by Plaintiffs, and as recognized by this Court, although Paxil had been approved for adult usage by the FDA, GSK had never sought approval for pediatric usage. In turn, the FDA's disclosure requirements never mandated the submission of any studies regarding effects on adolescents. Absent such FDA approval for pediatric usage and in the face of evidence showing risks inherent in known off-label Paxil use, GSK could have unilaterally changed its label to add a warning or simply sought to warn the medical community via "Dear Doctor" letters. See Perry v. Novartis, 456 F. Supp. 2d 678, 682 (E.D. Pa. 2006) ("The addition to labeling and advertising of additional warnings, as well as contraindications, adverse reactions, and precautions regarding the drug, or the issuance of letters directed to health care professionals (e.g., 'Dear Doctor' letters containing such information) is not prohibited by [FDA]

regulations.") (quoting 44 Fed. Reg. 37434, 37447 (June 26, 1979)).[38] Yet, it allegedly chose not to do so. It is this claimed deliberate failure to disclose such adverse events to the medical community – not any "fraud on the FDA" – that supports Plaintiffs' claims for punitive damages.[39]

In turn, such allegations find evidentiary support in the record. Beyond the evidence already discussed throughout this opinion showing that GSK knew of the risk of pediatric suicidality as of 1998, internal GSK documents suggest that Defendant acted with a wanton and willful disregard for the safety of its consumers. In the most telling of these documents, dated October of 1998, Defendant, discussing the problematic results of its Study 329, stated as follows:

> **TARGET:** To effectively manage the dissemination of these data in order to minimise [sic] any potential negative commercial impact.
>
> **PROPOSALS**
> - Based on the current data from Studies 377 and 329, and following consultation with SB country regulatory and marketing groups, no regulatory submissions will be made to obtain either efficacy or safety statements relating to adolescent depression at this time. However data (especially safety data) from these studies may be included in any future regulatory submissions, provided that we are able to go on and generate robust approvable efficacy data. The rationale for not attempting to obtain a safety statement at this time is as follows;
>
> i) regulatory agencies would not approve a statement indicating that there

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[38] Indeed, contrary to its claims that it could not have acted outside FDA approval, GSK ultimately did send "Dear Doctor" letters regarding risks in pediatric use of Paxil, in May 2004, prior to the issuance of any FDA-approved labeling changes. (Pls.' Ex. 64.)

[39] Defendant repeats arguments made in its preemption summary judgment motion that, as of September 2002, the FDA had found no reasonable evidence of an association between Paxil and increased suicidal thoughts by pediatric patients. This argument was fully addressed and rejected by this Court in Knipe, 2008 WL 4090995, at *22-24.

are no safety issues in adolescents, as this could be seen as promoting off-label use.

ii) it would be commercially unacceptable to include a statement that efficacy had not been demonstrated, as this would undermine the profile of paroxetine.

- Positive data from Study 329 will be published in abstract form at the ECNP (Paris, November 1998) and a full manuscript of the 329 data will be progressed.

(Pls.' Ex. 18.)[40] Given such evidence, Plaintiffs may be able to establish at trial that Defendant knew of the risks of pediatric use of its drug, yet failed to warn solely to increase the commercial profitability of Paxil. Such proof would constitute clear and convincing evidence of actual malice, which is not preempted by federal law. Accordingly, the Court denies Defendant's motion for summary judgment on this claim.

IV. CONCLUSION

In reaching the foregoing conclusions, the Court emphasizes that we make no definitive findings regarding liability. Rather, faced with literally hundreds of pages of both exhibits and legal briefing, the Court recognizes the presence of multiple genuine, indeed complicated, issues of material fact that must be resolved by a jury after a full trial on the merits. Accordingly, although the Court grants summary judgment on several minor claims, we decline to dismiss the bulk of the case at this juncture. An appropriate order follows.

[40] Again, Defendant cites evidence to dispute Plaintiff's assertions that GSK promoted Paxil for treating pediatric conditions. (Def.'s Reply Br. 21.) Such evidentiary disputes, however, highlight the existence of a genuine issue of material fact to be resolved by a jury.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

MARION L. KNIPE, Individually and as Administratrix and Administratrix Ad Prosequendum of the Estate of HAROLD STANLEY JAKE GARRISON, Deceased, and HAROLD L. GARRISON, JR., Individually,	:	CIVIL ACTION
Plaintiffs,	:	
v.	:	
	:	NO. 06-3024
SMITHKLINE BEECHAM d/b/a GLAXOSMITHKLINE,	:	
Defendant.	:	

ORDER

AND NOW, this *30th* day of *September*, 2008, upon consideration of the Motion of Defendant GlaxoSmithKline ("GSK") for Summary Judgment on Plaintiffs' Causes of Action (Doc. No. 62); the Response of Plaintiffs Harold L. Garrison, Jr., individually, and Marion Knipe, individually and as administratrix and administratrix *ad prosequendum* of the Estate of Harold Stanley Jake Garrison (Doc. No. 99), and Defendant's Reply Brief (Doc. No. 119), together with Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of Its Motion for Summary Judgment (Causes of Action) (Doc. No. 106) and Defendant's Response thereto (Doc. No. 116), it is hereby **ORDERED** as follows:

1. Plaintiffs' Motion to Strike Evidence Submitted by GSK in Support of Its Motion for Summary Judgment is **DENIED**;

2. Defendant's Motion for Summary Judgment on Plaintiffs' Causes of Action is **GRANTED IN PART** and **DENIED IN PART** as follows:

a. With respect to Plaintiffs' claims for fraud and negligent misrepresentation, Defendant's motion for summary judgment is **GRANTED** to the extent that Plaintiffs base those claims on the allegation that they were injured by Paxil's false or misleading warnings, but **DENIED** to the extent that Plaintiffs base those claims on the allegation that they were injured by Defendant's allegedly false and misleading advertising campaign for Paxil;

b. With respect to Plaintiffs' claims for off-label promotion of Paxil, Defendant's motion for summary judgment is **DENIED**;

c. With respect to Plaintiffs' claims for breach of express warranty, Defendant's motion for summary judgment is **DENIED**;

d. With respect to Plaintiffs' claim for negligent pharmaco-vigilance, Defendant's motion for summary judgment is **GRANTED**;

e. With respect to Plaintiffs' products liability claim for inadequate warnings under the New Jersey Products Liability Act, N.J. STAT. ANN. 2A:58C-1, *et seq.*, Defendant's motion for summary judgment is **DENIED**; and

f. With respect to Plaintiffs' claim for punitive damages, Defendant's motion for summary judgment is **DENIED**.

It is so **ORDERED**.

BY THE COURT:

s/ Ronald L. Buckwalter
RONALD L. BUCKWALTER, S.J.